

Table 1: Anonymised case level extraction of all UK cases where the reported medical device is a an implantable cardioverter defibrillators (GMDN/CT codes 35852, 37265, 47940, CT258) between 1 January 2000 up to and including 10 July 2026

Case	First Submission Year	Admin Info Event Classification	GMDN Code	GMDN Name	GMDN CT Code	GMDN CT Name	Patient As Reported IMDRF Code	Patient As Reported IMDRF Term	Clinical Event As Reported IMDRF Code	Clinical Event As Reported IMDRF Term	Device Explanted From Date	Device Explanted To Date
1	2004		35852	Single-chamber implantable defibrillator	CT141	Electrodes/Leads and associated devices	F1903	Device Explanation	A0406	Material Deformation		
					CT233	Surgical	F1903	Device Explanation	A0406	Material Deformation		
					CT2407	Active implantable	F1903	Device Explanation	A0406	Material Deformation		
					CT258	Implantable defibrillators	F1903	Device Explanation	A0406	Material Deformation		
					CT263	Cardiographs and associated devices	F1903	Device Explanation	A0406	Material Deformation		
					CT3001	Implantable metal	F1903	Device Explanation	A0406	Material Deformation		
					CT3002	Implantable synthetic polymer	F1903	Device Explanation	A0406	Material Deformation		
					CT3007	Implantable ceramic	F1903	Device Explanation	A0406	Material Deformation		
					CT314	Electrically powered	F1903	Device Explanation	A0406	Material Deformation		
					CT321	Long-term surgical invasive	F1903	Device Explanation	A0406	Material Deformation		
					CT449	Generators and associated devices	F1903	Device Explanation	A0406	Material Deformation		
					CT981	Single use	F1903	Device Explanation	A0406	Material Deformation		
2	2005		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
3	2005		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
4	2005		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators						
5	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
6	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
7	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
8	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
9	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
10	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
11	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
12	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
13	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
14	2006				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A27	Appropriate Device Problem Term/Code not Available		
15	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
16	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
17	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
18	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
19	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
20	2008		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
21	2007				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A27	Appropriate Device Problem Term/Code not Available		
22	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
23	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
24	2008		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
25	2008		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
26	2008		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
27	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
28	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
29	2008		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
30	2009		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
31	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
32	2009				CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
33	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
34	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
35	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
36	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
37	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
38	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
39	2007				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A27	Appropriate Device Problem Term/Code not Available		
40	2008		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
41	2006				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
42	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
43	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
44	2008				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
45	2008				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
46	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
47	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
48	2009				CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
49	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
50	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
51	2009				CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
52	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
53	2009		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
54	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
55	2006				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
56	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
57	2007				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
58	2009		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
59	2009				CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		

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664	2007				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
665	2008				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
666	2009				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
667	2009				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
668	2009				CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
669	2008				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
670	2009				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
671	2007				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A27	Appropriate Device Problem Term/Code not Available		
672	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
673	2009				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
674	2009				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
675	2009				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
676	2009				CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
677	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
678	2010				CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
679	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
680	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A04	Material Integrity Problem		
681	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
682	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
683	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A14	Infusion or Flow Problem		
684	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
685	2010		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
686	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A04 A0404 A16 A1602	Material Integrity Problem Crack Protective Measures Problem Fail-Safe Problem		
687	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0709 A11T A1102	Electrical /Electronic Property Problem Device Sensing Problem Computer Software Problem Application Program Problem		
688	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0721	Electrical /Electronic Property Problem Circuit Failure		
689	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
690	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
691	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
692	2012	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	24/07/2012 24/07/2012	
693	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
694	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
695	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
696	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
697	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
698	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
699	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
700	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
701	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
702	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
703	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
704	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
705	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
706	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
707	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
708	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
709	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications		
710	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
711	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
712	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
713	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
714	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
715	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
716	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		

717	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
718	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
719	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
720	2012	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
721	2012	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
722	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
723	2012	All other reportable incidents			CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0708	Electrical /Electronic Property Problem Power Problem		
724	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
725	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A13 A26	Communication or Transmission Problem Insufficient Device Problem Information		
726	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
727	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
728	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
729	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
730	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
731	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
732	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
733	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0104 A07 A0709	Migration or Expulsion of Device Electrical /Electronic Property Problem Device Sensing Problem		
734	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
735	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
736	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
737	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
738	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
739	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
740	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
741	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
742	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
743	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
744	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
745	2011	All other reportable incidents			CT258	Implantable defibrillators	E2401	Insufficient Information	A09 A0907	Output Problem No Device Output	10/04/2011 10/04/2011	
746	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
747	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
748	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
749	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
750	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0104	Migration or Expulsion of Device		
751	2012				CT258	Implantable defibrillators			A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
752	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
753	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
754	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
755	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
756	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
757	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A04 A0405	Material Integrity Problem Degraded		
758	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
759	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
760	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
761	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
762	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
763	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
764	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		

765	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
766	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
767	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
768	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
769	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
770	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
771	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem		
772	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0907	No Device Output		
773	2012	All other reportable incidents			CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
774	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	11/11/2011	
775	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A0708	Power Problem	11/11/2011	
776	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
777	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A12	Connection Problem		
778	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
779	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
780	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
781	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
782	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
783	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2109	Implant Pain	A26	Insufficient Device Problem Information		
784	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
785	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A1104	Computer Operating System Problem		
786	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
787	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
788	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
789	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
790	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
791	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
792	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
793	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
794	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0506	Hemorrhage/Blood Loss/Bleeding	A26	Insufficient Device Problem Information		
795	2011	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
796	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
797	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
798	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
799	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
800	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
801	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	11/07/2011	
802	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	11/07/2011	
803	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
804	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
805	2011	All other reportable incidents			CT258	Implantable defibrillators	E0514	Thrombosis/Thrombus	A26	Insufficient Device Problem Information		
806	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/06/2011	
807	2011	Death			CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A0708	Power Problem	25/06/2011	
808	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
809	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E1906	Unspecified Infection	A26	Insufficient Device Problem Information		
810	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2104	Electric Shock	A26	Insufficient Device Problem Information		
811	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
							F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
							E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A11	Computer Software Problem		
									A1102	Application Program Problem		
									A1104	Computer Operating System Problem		
									A26	Insufficient Device Problem Information		

812	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
813	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E1906	Unspecified Infection	A26	Insufficient Device Problem Information		
814	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
815	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
816	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
817	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2007	Fail	A26	Insufficient Device Problem Information		
818	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
819	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
820	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
821	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
822	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0708 A09 A090404	Electrical /Electronic Property Problem Power Problem Output Problem Output Above Specifications		
823	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
824	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
825	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
826	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
827	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
828	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
829	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
830	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
831	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
832	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
833	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
834	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
835	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
836	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
837	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
838	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
839	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
840	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
841	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
842	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
843	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
844	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
845	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
846	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
847	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
848	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A23	Use of Device Problem		
849	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A05 A0501 A09 A0908	Mechanical Problem Detachment of Device or Device Component Output Problem Incorrect, Inadequate or Imprecise Result or Readings		
850	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
851	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
852	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
853	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A10 A1006	Temperature Problem Thermal Decomposition of Device		
854	2011	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	08/08/2011 08/08/2011	
855	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
856	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
857	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
858	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		

859	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
860	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
861	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
862	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
863	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
864	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
865	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
866	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
867	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
868	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
869	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
870	2012	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	14/05/2012 14/05/2012	
871	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
872	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
873	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A09 A090404 A12 A1204 A15 A150301	Output Problem Output Above Specifications Connection Problem Failure to Disconnect Activation, Positioning or Separation Problem Separation Failure		
874	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
875	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
876	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A09 A090404	Output Problem Output Above Specifications		
877	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A01 A17	Patient Device Interaction Problem Compatibility Problem		
878	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
879	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
880	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
881	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
882	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
883	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
884	2012	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
885	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
886	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
887	2012	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	20/09/2012 20/09/2012	
888	2012	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	23/08/2012 23/08/2012	
889	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
890	2012	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
891	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
892	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
893	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
894	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
895	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
896	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
897	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
898	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
899	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
900	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
901	2011	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	16/03/2011 16/03/2011	
902	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
903	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
904	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		

905	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A26	Insufficient Device Problem Information		
906	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
907	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
908	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
909	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
910	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
911	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
912	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A23	Use of Device Problem		
913	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
914	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A09	Output Problem		
915	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
916	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
917	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0709	Device Sensing Problem		
918	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
919	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
920	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
921	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
922	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
923	2011	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	17/04/2011	
924	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information	17/04/2011	
925	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
926	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
927	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
928	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
929	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A13	Communication or Transmission Problem		
930	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
931	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
932	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
933	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
934	2011		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
935	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A13	Communication or Transmission Problem		
936	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A15	Activation, Positioning or Separation Problem		
937	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A150203	Difficult or Delayed Positioning		
									A07	Electrical /Electronic Property Problem		
938	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A0709	Device Sensing Problem		
									A26	Insufficient Device Problem Information		
939	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
940	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
941	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
942	2011	All other reportable incidents			CT258	implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
943	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
									A26	Insufficient Device Problem Information		
944	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem		
945	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0721	Circuit Failure		
									A26	Insufficient Device Problem Information		
946	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
947	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
948	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
949	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
950	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
951	2012		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		

952	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
953	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
954	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
955	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A09 A090404	Output Problem Output Above Specifications		
956	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09 A0907 A1304 A26	Output Problem No Device Output Telemetry Discrepancy Insufficient Device Problem Information		
957	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
958	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A13 A26	Communication or Transmission Problem Insufficient Device Problem Information		
959	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07 A0708	Electrical /Electronic Property Problem Power Problem		
960	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
961	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
962	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
963	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
964	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
965	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
966	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
967	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
968	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2109	Implant Pain	A26	Insufficient Device Problem Information		
969	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
970	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
971	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
972	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
973	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
974	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
975	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
976	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A26	Insufficient Device Problem Information		
977	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
978	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
979	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
980	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
981	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
982	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
983	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
984	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
985	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
986	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
987	2011	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	11/08/2011	
988	2011	Death		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information	11/08/2011	
989	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
990	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
991	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
992	2012	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/11/2012	
993	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/11/2012	
994	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
995	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
996	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
997	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
998	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		

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1048	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1049	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1050	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
1051	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1052	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1053	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1054	2011			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0104	Migration or Expulsion of Device		
1055	2011	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0708	Electrical /Electronic Property Problem Power Problem	23/08/2011	
1056	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	23/08/2011	
1057	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1058	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1059	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1060	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1061	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	insufficient Information	A26	Insufficient Device Problem Information		
1062	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1063	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1064	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1065	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1066	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1067	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A09 A0908	Output Problem Incorrect, Inadequate or Imprecise Result or Readings		
1068	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1069	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
1070	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1071	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
1072	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1073	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1074	2012			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1603	Bone Fracture(s)	A26	Insufficient Device Problem Information		
1075	2014	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1076	2014	All other reportable incidents				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	13/03/2014	
1077	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A09 A0908	Output Problem Incorrect, Inadequate or Imprecise Result or Readings	13/03/2014	
1078	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1079	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1104	Computer Operating System Problem		
1080	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1081	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1082	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1083	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1084	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1085	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1086	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1087	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1088	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1089	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1090	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1091	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1092	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1093	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A24 A26	No Apparent Device Problem Insufficient Device Problem Information		
1094	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1095	2013					CT258	Implantable defibrillators	F21	Unexpected Deterioration	A07 A0709 A09	Electrical /Electronic Property Problem Device Sensing Problem Output Problem		

1096	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0390404	Output Above Specifications		
1097	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1098	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1099	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0202	Emotional Changes	A26	Insufficient Device Problem Information		
1100	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1101	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1102	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1103	2013					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
1104	2013					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
1105	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A0708	Electrical /Electronic Property Problem		
1106	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
1107	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Insufficient Device Problem Information		
1108	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Device Sensing Problem		
1109	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1110	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1111	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1112	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A15	Activation, Positioning or Separation Problem		
1113	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A150301	Separation Failure		
1114	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1115	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1116	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1117	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1118	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0506	Hemorrhage/Blood Loss/Bleeding	A24	No Apparent Device Problem		
1119	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1120	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1121	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1122	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1123	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
1124	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1125	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1126	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1127	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1128	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1129	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1130	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1131	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1132	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1133	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1134	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1135	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1136	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
1137	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A0708	Power Problem		
1138	2013	All other reportable incidents				CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1139	2013	All other reportable incidents				CT258	Implantable defibrillators	E0139	Unspecified Nervous System Problem	A07	Electrical /Electronic Property Problem		
1140	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A0708	Power Problem		
1141	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1142	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1143	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1144	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		

1145	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1146	2013					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1147	2013					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1148	2013	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	14/10/2013 14/10/2013	
1149	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1150	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1151	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F14	Prolonged Episode of Care	A09 A090404	Output Problem Output Above Specifications		
1152	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1153	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1154	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1155	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1156	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
1157	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1158	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1159	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1160	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1161	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1162	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1163	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1164	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1165	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
1166	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1167	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1168	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1169	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1170	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
1171	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1172	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1173	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1174	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1175	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1176	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
1177	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1178	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1179	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1180	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1181	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1182	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1183	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A05 A0506	Mechanical Problem Mechanical Jam	05/06/2013 05/06/2013	
1184	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1185	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
1186	2014					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1187	2013	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	22/10/2013 22/10/2013	
1188	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A24 A26	No Apparent Device Problem Insufficient Device Problem Information		
1189	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1190	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1191	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1192	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		

1193	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1194	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1195	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1196	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication		A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1197	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A26	Insufficient Device Problem Information		
1198	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care		A07	Electrical /Electronic Property Problem		
1199	2014					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0708	Power Problem		
1200	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0709	Device Sensing Problem		
1201	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction		A07	Electrical /Electronic Property Problem Device Sensing Problem		
1202	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1203	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information		A26	Insufficient Device Problem Information		
1204	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information		A26	Insufficient Device Problem Information		
1205	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A1304	Telemetry Discrepancy		
1206	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1207	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction		A1304	Telemetry Discrepancy		
1208	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1209	2013		All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1210	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2104	Electric Shock		A07	Electrical /Electronic Property Problem		
1211	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0506	Hemorrhage/Blood Loss/Bleeding		A0708	Power Problem		
1212	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A24	No Apparent Device Problem		
1213	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1214	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration		A24	No Apparent Device Problem		
1215	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication		A26	Insufficient Device Problem Information		
1216	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration		A26	Insufficient Device Problem Information		
1217	2013					CT258	implantable defibrillators	F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem		
1218	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction		A0708	Power Problem		
1219	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1220	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information		A26	Insufficient Device Problem Information		
1221	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication		A26	Insufficient Device Problem Information		
1222	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1223	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1224	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1225	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1226	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1227	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1228	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication		A26	Insufficient Device Problem Information		
1229	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication		A26	Insufficient Device Problem Information		
1230	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1231	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1232	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1233	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication		A26	Insufficient Device Problem Information		
1234	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1235	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction		A26	Insufficient Device Problem Information		
1236	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1237	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1238	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1239	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1240	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care		A07	Electrical /Electronic Property Problem		
											A0708	Power Problem		

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1289	2014				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
1290	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A0708	Power Problem		
									A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT1150	Defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT233	Surgical	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2406	Implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2407	Active implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2985	Active	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT314	Electrically powered	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT440	Generators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT981	Single use	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
1291	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
1292	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
1293	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
1294	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
1295	2014	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	08/09/2014	
									A07	Electrical /Electronic Property Problem	08/09/2014	
									A0708	Power Problem	08/09/2014	
									A0709	Device Sensing Problem	08/09/2014	
1296	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	16/09/2012	
									A0708	Power Problem	16/09/2012	
1297	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem		
1298	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem	
									A26	Insufficient Device Problem Information		
1299	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	
									A0708	Power Problem		
1300	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
1301	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
1302	2013	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/06/2013	
									A0708	Power Problem	20/06/2013	
1303	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem		
1304	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information	
1305	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A07	Electrical /Electronic Property Problem	
									A0708	Power Problem		
1306	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/12/2012	
									A0708	Power Problem	22/12/2012	
1307	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
1308	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
1309	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
1310	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	

1311	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1312	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Device Sensing Problem		
1313	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1314	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1315	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1316	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1317	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11 A1102	Computer Software Problem Application Program Problem		
1318	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1319	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1320	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT233	Surgical	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT2406	Implantable	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT2985	Active	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT981	Single use	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A11 A1102	Computer Software Problem Application Program Problem		
1321	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1322	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1323	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906 F1905	Unspecified Infection Device Revision or Replacement	A01 A01 A17	Patient Device Interaction Problem Compatibility Problem Patient Device Interaction Problem		
					CT1147	Defibrillators and associated devices	E1906 F1905	Unspecified Infection Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT1150	Defibrillators	E1906 F1905	Unspecified Infection Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	E1906 F1905	Unspecified Infection Device Revision or Replacement	A01 A01 A17	Patient Device Interaction Problem Compatibility Problem Patient Device Interaction Problem		
					CT145	Cardiovascular devices	E1906 F1905	Unspecified Infection Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		

					CT233	Surgical	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2406	Implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2407	Active implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2985	Active	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT314	Electrically powered	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT981	Single use	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
1324	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1325	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1326	2013	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/10/2013	
1327	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	22/10/2013	
1328	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
1329	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F14	Prolonged Episode of Care	A0104	Migration or Expulsion of Device		
									A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
									A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		

					CT1147	Defibrillators and associated devices	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT1150	Defibrillators	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT145	Cardiovascular devices	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT233	Surgical	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT2406	Implantable	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT2407	Active implantable	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT263	Cardiographs and associated devices	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT2726	Physiological monitoring/measuring devices	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT2727	Active implant devices/ancillaries	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT2866	Implantable cardiac electrical stimulators	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT2985	Active	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT3001	implantable metal	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT3006	Implantable inorganic material	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT3007	Implantable ceramic	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT314	Electrically powered	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT321	Long-term surgical invasive	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT449	Generators and associated devices	F14	Prolonged Episode of Care	A17	Compatibility Problem		
					CT981	Single use	F14	Prolonged Episode of Care	A01	Patient Device Interaction Problem		
					CT983	Surgical invasive	F14	Prolonged Episode of Care	A17	Compatibility Problem		
1330	2014				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A17	Compatibility Problem		
1331	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
1332	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1333	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
1334	2014				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
1335	2013				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
1336	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
1337	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0721	Circuit Failure	30/09/2014	
1338	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A11	Computer Software Problem	30/09/2014	
1339	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A1102	Application Program Problem		
1340	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1341	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1342	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1343	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1344	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem		
1345	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
1346	2014				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
1347	2013		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices			A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators			A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices			A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices			A0709	Device Sensing Problem		

					CT233	Surgical				A07	Electrical /Electronic Property Problem		
					CT2406	Implantable				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2407	Active implantable				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2985	Active				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT3001	Implantable metal				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT3007	Implantable ceramic				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT314	Electrically powered				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT449	Generators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT981	Single use				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT983	Surgical invasive				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1348	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care		A01	Patient Device Interaction Problem		
1349	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A17	Compatibility Problem		
1350	2013			Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1351	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1352	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1353	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A26	Insufficient Device Problem Information		
1354	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1355	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1356	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1357	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1358	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem		
1359	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1360	2014				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A07	Electrical /Electronic Property Problem		
1361	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
1362	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1363	2014				CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0721	Circuit Failure		
1364	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1365	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1366	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem		
1367	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1368	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	18/10/2012	
1369	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem	18/10/2012	
1370	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1371	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1372	2013				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A07	Electrical /Electronic Property Problem		
1373	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1374	2013	All other reportable incidents			CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction		A26	Insufficient Device Problem Information		
1375	2013	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	08/03/2013	
										A0708	Power Problem	08/03/2013	
										A07	Electrical /Electronic Property Problem	10/01/2013	

									A0708	Power Problem	10/01/2013	
1376	2013	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/01/2013	
1377	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	25/01/2013	
1378	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1379	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1380	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A09	Output Problem		
1381	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
1382	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
1383	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A07	Electrical /Electronic Property Problem	28/04/2014	
					CT1147	Defibrillators and associated devices			A0708	Power Problem	28/04/2014	
					CT1150	Defibrillators			A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices			A0708	Power Problem		
					CT145	Cardiovascular devices			A26	Insufficient Device Problem Information		
					CT233	Surgical			A26	Insufficient Device Problem Information		
					CT2406	Implantable			A26	Insufficient Device Problem Information		
					CT2407	Active implantable			A1304	Telemetry Discrepancy		
					CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
					CT263	Cardiographs and associated devices			A1304	Telemetry Discrepancy		
					CT2726	Physiological monitoring/measuring devices			A26	Insufficient Device Problem Information		
					CT2727	Active implant devices/ancillaries			A1304	Telemetry Discrepancy		
					CT2750	Implantable cardiac electrical stimulators and associated devices			A26	Insufficient Device Problem Information		
					CT2866	Implantable cardiac electrical stimulators			A1304	Telemetry Discrepancy		
					CT2985	Active			A26	Insufficient Device Problem Information		
					CT3001	Implantable metal			A1304	Telemetry Discrepancy		
					CT3002	Implantable synthetic polymer			A26	Insufficient Device Problem Information		
					CT3006	Implantable inorganic material			A1304	Telemetry Discrepancy		
					CT3007	Implantable ceramic			A26	Insufficient Device Problem Information		
					CT314	Electrically powered			A1304	Telemetry Discrepancy		
					CT321	Long-term surgical invasive			A26	Insufficient Device Problem Information		
					CT449	Generators and associated devices			A1304	Telemetry Discrepancy		
					CT981	Single use			A26	Insufficient Device Problem Information		
					CT983	Surgical invasive			A1304	Telemetry Discrepancy		
1384	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1385	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1386	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1387	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1388	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
1389	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A0708	Power Problem		
1390	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1391	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
1392	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A0708	Power Problem		
1393	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
1394	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem		
1395	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
1396	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1397	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		

1398	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1399	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1400	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1401	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	02/10/2012 02/10/2012	
1402	2013				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1403	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1404	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	23/05/2014 23/05/2014	
1405	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1406	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1407	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1408	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1409	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1410	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1411	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1412	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1413	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1414	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1415	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1416	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1417	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
1418	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1419	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1420	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT1150	Defibrillators	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT145	Cardiovascular devices	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT233	Surgical	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT2406	Implantable	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT2407	Active implantable	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT258	implantable defibrillators	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT2985	Active	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT3001	Implantable metal	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT3007	Implantable ceramic	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT314	Electrically powered	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT449	Generators and associated devices	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT981	Single use	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
					CT983	Surgical invasive	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		

1421	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1422	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1423	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13 A26	Communication or Transmission Problem Insufficient Device Problem Information		
1424	2013					CT258	Implantable defibrillators	E2401	Insufficient Information	A13 A26	Communication or Transmission Problem Insufficient Device Problem Information		
1425	2013					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1426	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1427	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1428	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1429	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2109	Implant Pain	A0104 A07 A0709	Migration or Expulsion of Device Electrical /Electronic Property Problem Device Sensing Problem		
								F14	Prolonged Episode of Care	A0104 A07 A0709	Migration or Expulsion of Device Electrical /Electronic Property Problem Device Sensing Problem		
1430	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1431	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1432	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1433	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1434	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1435	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1436	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
1437	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1438	2013					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1439	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A09 A090404	Output Problem Output Above Specifications		
1440	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1441	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1442	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1443	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1444	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1445	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1446	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1447	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1448	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1449	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	24/10/2014	
1450	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	24/10/2014	
1451	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1452	2013	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	11/02/2013	
1453	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	11/02/2013	
1454	2014	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1455	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1456	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1457	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1458	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1459	2014	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1460	2014	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1461	2013			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1462	2014	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1463	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1464	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1465	2014			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		

1466	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1467	2014				CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1468	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1469	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1470	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0708	Electrical /Electronic Property Problem Power Problem	14/10/2014 14/10/2014	
1471	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1472	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1473	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1474	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1475	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A09 A090404	Output Problem Output Above Specifications		
1476	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A13 A1304 A26	Communication or Transmission Problem Telemetry Discrepancy Insufficient Device Problem Information		
1477	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1478	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1479	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1480	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1481	2014	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1482	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1483	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1484	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1485	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1486	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1487	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1488	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1489	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1490	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1491	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13 A26	Communication or Transmission Problem Insufficient Device Problem Information		
1492	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A09 A090404	Output Problem Output Above Specifications		
1493	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1494	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07 A0708	Electrical /Electronic Property Problem Power Problem		
1495	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1496	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1497	2014	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A09 A0907	Output Problem No Device Output	04/02/2014 04/02/2014	
1498	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A0907	Output Problem No Device Output		
1499	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1500	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1501	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1502	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1503	2013				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A05 A0501 A07 A0709	Mechanical Problem Detachment of Device or Device Component Electrical /Electronic Property Problem Device Sensing Problem		
1504	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1505	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1506	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1507	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1508	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1509	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1510	2014				CT258	Implantable defibrillators	E2401	Insufficient Information	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1511	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A01 A0104	Patient Device Interaction Problem Migration or Expulsion of Device	26/10/2014 26/10/2014	

				F1905	Device Revision or Replacement	A17	Compatibility Problem	26/10/2014		
						A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT1147	Defibrillators and associated devices		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT1150	Defibrillators		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT1141	Electrodes/Leads and associated devices		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT1145	Cardiovascular devices		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT233	Surgical		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT2406	Implantable		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT2407	Active implantable		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT258	Implantable defibrillators		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT263	Cardiographs and associated devices		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT2726	Physiological monitoring/measuring devices		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT2727	Active implant devices/ancillaries		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT2750	Implantable cardiac electrical stimulators and associated devices		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT2866	Implantable cardiac electrical stimulators		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT2985	Active		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
			F1905		Device Revision or Replacement	A001	Patient Device Interaction Problem	26/10/2014		
						A0104	Migration or Expulsion of Device	26/10/2014		
						A17	Compatibility Problem	26/10/2014		
CT3001	Implantable metal		E1906		Unspecified Infection	A001	Patient Device Interaction Problem	26/10/2014		

					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2985	Active	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT314	Electrically powered	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT981	Single use	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
1513	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1514	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1515	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	P21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1516	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1517	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1518	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1519	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1520	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1521	2013	All other reportable incidents			CT258	Implantable defibrillators			A07 A0708	Electrical /Electronic Property Problem Power Problem		
1522	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1523	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F15	Recognized Device or Procedural Complication	A01	Patient Device Interaction Problem		
					CT1147	Defibrillators and associated devices	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
					CT1150	Defibrillators	F15	Recognized Device or Procedural Complication	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	F15	Recognized Device or Procedural Complication	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT145	Cardiovascular devices	F15	Recognized Device or Procedural Complication	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT233	Surgical	F15	Recognized Device or Procedural Complication	A01	Patient Device Interaction Problem		

					CT2406	Implantable	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2407	Active implantable	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT263	Cardiographs and associated devices	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2726	Physiological monitoring/measuring devices	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2727	Active implant devices/ancillaries	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2866	Implantable cardiac electrical stimulators	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2985	Active	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3001	Implantable metal	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3002	Implantable synthetic polymer	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3006	Implantable inorganic material	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3007	Implantable ceramic	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT314	Electrically powered	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT321	Long-term surgical invasive	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT449	Generators and associated devices	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT981	Single use	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT983	Surgical invasive	F15	Recognized Device or Procedural Complication	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
1524	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT1150	Defibrillators	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT1141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT233	Surgical	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT2406	Implantable	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT2407	Active implantable	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT2985	Active	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT3001	Implantable metal	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT314	Electrically powered	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT449	Generators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT981	Single use	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
					CT983	Surgical invasive	E1906	Unspecified Infection	A17	Compatibility Problem	24/04/2014	
									A01	Patient Device Interaction Problem	24/04/2014	
1525	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
									A0504	Leak/Splash		
1526	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		

1527	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A16	Protective Measures Problem	31/01/2014	
1528	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1602	Fail-Safe Problem	31/01/2014	
1529	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/02/2013	
1530	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A0708	Power Problem	22/02/2013	
1531	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	28/01/2014	
1532	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem	28/01/2014	
1533	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1534	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
1535	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0709	Device Sensing Problem		
1536	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
1537	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
1538	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1539	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
1540	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1541	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1542	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1543	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1544	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
1545	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1546	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1547	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1548	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1549	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1550	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1551	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT233	Surgical	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2406	Implantable	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2985	Active	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT981	Single use	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		

						CT983	Surgical invasive	F1905	Device Revision or Replacement	A17	Compatibility Problem		
						CT258	Implantable defibrillators			A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
1552	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1553	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
1554	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A0708	Power Problem			
									A26	Insufficient Device Problem Information			
1555	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information			
1556	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information			
1557	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1558	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1559	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1560	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1561	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information			
1562	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information			
1563	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information			
1564	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1565	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
1566	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
									A0708	Power Problem			
1567	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		04/03/2014	
									A0709	Device Sensing Problem		04/03/2014	
1568	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information			
1569	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1570	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information			
1571	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information			
1572	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1573	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information			
1574	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information			
1575	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A16	Protective Measures Problem			
									A1602	Fail-Safe Problem			
1576	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information			
1577	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information			
1578	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information			
1579	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information			
1580	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information			
1581	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information			
1582	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		16/08/2013	
									A0708	Power Problem		16/08/2013	
1583	2013	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		07/05/2013	
									A0708	Power Problem		07/05/2013	
1584	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information			
1585	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information			
1586	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1587	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1588	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
1589	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
									A0708	Power Problem			
1590	2014	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
									A0708	Power Problem			
1591	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information			
1592	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information			
1593	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information			
1594	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information			
1595	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information			
1596	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information			
1597	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1598	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information			
1599	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0104	Migration or Expulsion of Device			

									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
1600	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							E2109	Implant Pain	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
1601	2013	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	17/02/2013	
									A0708	Power Problem	17/02/2013	
1602	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
1603	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1604	2013				CT258	implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
1605	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A17	Compatibility Problem		
									A26	Insufficient Device Problem Information		
1606	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1607	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1608	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1609	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1610	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
1611	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
1612	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F14	Prolonged Episode of Care	A13	Communication or Transmission Problem		
							F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
									A13	Communication or Transmission Problem		
									A26	Insufficient Device Problem Information		
1613	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1614	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
1615	2013	All other reportable incidents			CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	18/03/2013	
									A0708	Power Problem	18/03/2013	
1616	2013	All other reportable incidents			CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	29/04/2013	
									A0708	Power Problem	29/04/2013	
1617	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1618	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1619	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1620	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1621	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1622	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1623	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1624	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1625	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1626	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1627	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1628	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1629	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1630	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
1631	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1632	2014				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	04/06/2014	
									A26	Insufficient Device Problem Information	04/06/2014	
1633	2013				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1634	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
									A13	Communication or Transmission Problem		
									A26	Insufficient Device Problem Information		
1635	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
1636	2013				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1637	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1638	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1639	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1640	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1641	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		

1642	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1643	2013				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1644	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1645	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1646	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1647	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/07/2014 09/07/2014	
1648	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1649	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1650	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1651	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1652	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1653	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1654	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1655	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1656	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1657	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1658	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1659	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1660	2013				CT258	implantable defibrillators			A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1661	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1662	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1663	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1664	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1665	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1666	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1667	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104 F14	Electric Shock Prolonged Episode of Care	A09 A090404 A09 A090404	Output Problem Output Above Specifications Output Problem Output Above Specifications		
1668	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1669	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1670	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
1671	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1672	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT1147	Defibrillators and associated devices	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT1150	Defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT1141	Electrodes/Leads and associated devices	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT1145	Cardiovascular devices	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT233	Surgical	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT2406	Implantable	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT2407	Active implantable	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT263	Cardiographs and associated devices	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT2726	Physiological monitoring/measuring devices	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT2727	Active implant devices/ancillaries	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT2866	Implantable cardiac electrical stimulators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT2985	Active	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT3001	Implantable metal	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT3002	Implantable synthetic polymer	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT3006	Implantable inorganic material	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT3007	Implantable ceramic	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT314	Electrically powered	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT321	Long-term surgical invasive	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT449	Generators and associated devices	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT981	Single use	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
					CT983	Surgical invasive	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1673	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
1674	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1675	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1676	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

									A0709	Device Sensing Problem		
1677	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1678	2014		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
1679	2013	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	28/08/2013	
1680	2014	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	28/08/2013	
									A07	Electrical /Electronic Property Problem	18/07/2014	
									A0708	Power Problem	18/07/2014	
1681	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT1147	Defibrillators and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT1150	Defibrillators	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT141	Electrodes/Leads and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT145	Cardiovascular devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT233	Surgical	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT2406	Implantable	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT2407	Active implantable	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT258	Implantable defibrillators	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT263	Cardiographs and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT2726	Physiological monitoring/measuring devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT2727	Active implant devices/ancillaries	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT2886	Implantable cardiac electrical stimulators	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT2985	Active	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT3001	Implantable metal	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT3002	Implantable synthetic polymer	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT3006	Implantable inorganic material	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT3007	Implantable ceramic	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
					CT314	Electrically powered	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	
									A07	Electrical /Electronic Property Problem	01/08/2014	
									A0709	Device Sensing Problem	01/08/2014	

					CT321	Long-term surgical invasive	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	01/08/2014	
					CT449	Generators and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	01/08/2014	
					CT981	Single use	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	01/08/2014	
					CT983	Surgical invasive	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem	01/08/2014	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	01/08/2014	
1682	2014		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices			A0709	Device Sensing Problem		
					CT1150	Defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2886	Implantable cardiac electrical stimulators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
1683	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1684	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1685	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1686	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1687	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
1688	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
1689	2013		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A26	Insufficient Device Problem Information		
1690	2013		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		

					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
1691	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1692	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1693	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1694	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1695	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1696	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1697	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
1698	2016	All other reportable incidents			CT258	implantable defibrillators			A0709	Device Sensing Problem		
1699	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem	29/07/2016	
1700	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0708	Power Problem	29/07/2016	
1701	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0709	Device Sensing Problem		
1702	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1703	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
1704	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0708	Power Problem		
1705	2015	All other reportable incidents			CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem	18/12/2014	
1706	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0708	Power Problem	18/12/2014	
1707	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
1708	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0709	Device Sensing Problem		
1709	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
1710	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0708	Power Problem		
1711	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
1712	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0709	Device Sensing Problem		
1713	2015				CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
1714	2015				CT258	implantable defibrillators			A0708	Power Problem		
1715	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0709	Device Sensing Problem		
1716	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A24	No Apparent Device Problem		
1717	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		

1718	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1719	2015				CT258	implantable defibrillators				A07 A0708	Electrical /Electronic Property Problem Power Problem		
1720	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1721	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1722	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1723	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1724	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A01 A17	Patient Device Interaction Problem Compatibility Problem		
1725	2016	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1726	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT1147	Defibrillators and associated devices				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT1150	Defibrillators				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT141	Electrodes/Leads and associated devices				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT145	Cardiovascular devices				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT233	Surgical				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2406	Implantable				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2407	Active implantable				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT258	Implantable defibrillators				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT263	Cardiographs and associated devices				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2727	Active implant devices/ancillaries				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2985	Active				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3001	Implantable metal				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3002	Implantable synthetic polymer				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3006	Implantable inorganic material				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3007	Implantable ceramic				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT314	Electrically powered				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT321	Long-term surgical invasive				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT449	Generators and associated devices				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT981	Single use				A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT983	Surgical invasive				A01 A17	Patient Device Interaction Problem Compatibility Problem		
1727	2015				CT258	implantable defibrillators				A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
1728	2016	All other reportable incidents			CT258	implantable defibrillators				A07 A0708	Electrical /Electronic Property Problem Power Problem		
1729	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A09 A0907	Output Problem No Device Output		
1730	2016	TBD			CT258	Implantable defibrillators				A07 A0708	Electrical /Electronic Property Problem Power Problem		
1731	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07 A0708	Electrical /Electronic Property Problem Power Problem		
1732	2015				CT258	Implantable defibrillators				A07 A0708	Electrical /Electronic Property Problem Power Problem	04/05/2015	
1733	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1734	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A16 A1602	Protective Measures Problem Fail-Safe Problem		
1735	2016	All other reportable incidents			CT258	Implantable defibrillators				A07 A0708	Electrical /Electronic Property Problem Power Problem	03/03/2016	
1736	2015	All other reportable incidents			CT258	Implantable defibrillators				A07 A0708	Electrical /Electronic Property Problem Power Problem		
1737	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1738	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1739	2016	All other reportable incidents			CT258	Implantable defibrillators				A07 A0708	Electrical /Electronic Property Problem Power Problem	16/08/2016	

1740	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1741	2016	TBD			CT258	implantable defibrillators				A0708	Power Problem		
1742	2016	TBD			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
1743	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1744	2015				CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1745	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	06/09/2016	
1746	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem	06/09/2016	
1747	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
1748	2016	TBD	35852	Single-chamber implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem		
					CT1010	Cardiovascular physiology analysis/mapping devices				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT1147	Defibrillators and associated devices				A0709	Device Sensing Problem	14/06/2018	
					CT1150	Defibrillators				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT141	Electrodes/Leads and associated devices				A0709	Device Sensing Problem	14/06/2018	
					CT145	Cardiovascular devices				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT233	Surgical				A0709	Device Sensing Problem	14/06/2018	
					CT2406	Implantable				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT2407	Active implantable				A0709	Device Sensing Problem	14/06/2018	
					CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT263	Cardiographs and associated devices				A0709	Device Sensing Problem	14/06/2018	
					CT2726	Physiological monitoring/measuring devices				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT2727	Active implant devices/ancillaries				A0709	Device Sensing Problem	14/06/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT2866	Implantable cardiac electrical stimulators				A0709	Device Sensing Problem	14/06/2018	
					CT2985	Active				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT3001	implantable metal				A0709	Device Sensing Problem	14/06/2018	
					CT3002	implantable synthetic polymer				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT3006	Implantable inorganic material				A0709	Device Sensing Problem	14/06/2018	
					CT3007	Implantable ceramic				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT314	Electrically powered				A0709	Device Sensing Problem	14/06/2018	
					CT321	Long-term surgical invasive				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT449	Generators and associated devices				A0709	Device Sensing Problem	14/06/2018	
					CT981	Single use				A07	Electrical /Electronic Property Problem	14/06/2018	
					CT983	Surgical invasive				A0709	Device Sensing Problem	14/06/2018	
1749	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1750	2015				CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
1751	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem		
1752	2015				CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
1753	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1754	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1755	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
1756	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	02/06/2015	
1757	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem	02/06/2015	
1758	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1759	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1760	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
1761	2015				CT258	implantable defibrillators				A0709	Device Sensing Problem		
										A26	Insufficient Device Problem Information		
										A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		

1762	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	22/08/2016	
1763	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem	22/08/2016	
										A09	Output Problem		
1764	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A090404	Output Above Specifications		
										A26	Insufficient Device Problem Information		
1765	2016	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT1150	Defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT145	Cardiovascular devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT233	Surgical				A0708	Electrical /Electronic Property Problem		
										A07	Electrical /Electronic Property Problem		
					CT2406	Implantable				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT258	implantable defibrillators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2985	Active				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3001	implantable metal				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3002	implantable synthetic polymer				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3006	implantable inorganic material				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT981	Single use				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive				A0709	Device Sensing Problem		
1766	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	23/10/2015	
										A0708	Power Problem	23/10/2015	
1767	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1768	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1769	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1770	2016	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	22/08/2016	
										A0708	Power Problem	22/08/2016	
1771	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1772	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1773	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1774	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	17/06/2015	
										A0708	Power Problem	17/06/2015	
1775	2016	TBD			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1776	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1777	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem		
										A26	Insufficient Device Problem Information		
1778	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1779	2015	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A24	No Apparent Device Problem	20/12/2014	
										A26	Insufficient Device Problem Information	20/12/2014	
1780	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1781	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1782	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1783	2015	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	21/10/2015	

									A0708	Power Problem	21/10/2015	
1784	2015				CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
1785	2015				CT258	Implantable defibrillators			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
1786	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem	13/10/2015	
									A0708	Power Problem	13/10/2015	
1787	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT1147	Defibrillators and associated devices			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT1150	Defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT141	Electrodes/Leads and associated devices			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT145	Cardiovascular devices			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT233	Surgical			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT2406	Implantable			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT2407	Active implantable			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT263	Cardiographs and associated devices			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT2726	Physiological monitoring/measuring devices			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT2727	Active implant devices/ancillaries			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT2866	Implantable cardiac electrical stimulators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT2985	Active			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT3001	Implantable metal			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT3002	Implantable synthetic polymer			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT3006	Implantable inorganic material			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT3007	Implantable ceramic			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT314	Electrically powered			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT321	Long-term surgical invasive			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT449	Generators and associated devices			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT981	Single use			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
					CT983	Surgical invasive			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1788	2016	All other reportable incidents			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	19/08/2016	
1789	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem	19/08/2016	
									A11	Computer Software Problem		
1790	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A1102	Application Program Problem		
									A07	Electrical /Electronic Property Problem	17/08/2016	
1791	2016	All other reportable incidents			CT258	Implantable defibrillators			A0708	Power Problem	17/08/2016	
									A16	Protective Measures Problem	24/03/2016	
1792	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A1602	Fail-Safe Problem	24/03/2016	
									A07	Electrical /Electronic Property Problem	19/08/2016	
									A0708	Power Problem	19/08/2016	
1793	2016	Unanticipated serious deterioration in state of health			CT258	Implantable defibrillators			A16	Protective Measures Problem		
									A1602	Fail-Safe Problem		
1794	2015	All other reportable incidents			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	01/10/2015	
									A0708	Power Problem	01/10/2015	
1795	2015	All other reportable incidents			CT258	Implantable defibrillators			A16	Protective Measures Problem	09/11/2015	
									A1602	Fail-Safe Problem	09/11/2015	
1796	2015				CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1797	2015				CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1798	2016	All other reportable incidents			CT258	Implantable defibrillators			A16	Protective Measures Problem		
									A1602	Fail-Safe Problem		
1799	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	01/09/2015	
									A0708	Power Problem	01/09/2015	
1800	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1801	2015	All other reportable incidents			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1802	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1803	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1804	2016	All other reportable incidents			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	23/03/2016	
									A0709	Device Sensing Problem	23/03/2016	

1805	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1806	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1807	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem	29/05/2015	
1808	2016	TBD			CT258	Implantable defibrillators				A26	Insufficient Device Problem Information	29/05/2015	
1809	2016	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A26	Insufficient Device Problem Information		
					CT1147	Defibrillators and associated devices				A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators				A0708	Power Problem		
					CT141	Electrodes/Leads and associated devices				A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices				A0708	Power Problem		
					CT233	Surgical				A07	Electrical /Electronic Property Problem		
					CT2406	Implantable				A0708	Power Problem		
					CT2407	Active implantable				A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators				A0708	Power Problem		
					CT263	Cardiographs and associated devices				A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices				A0708	Power Problem		
					CT2727	Active implant devices/ancillaries				A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators				A0708	Power Problem		
					CT2985	Active				A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal				A0708	Power Problem		
					CT3002	Implantable synthetic polymer				A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material				A0708	Power Problem		
					CT3007	Implantable ceramic				A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered				A0708	Power Problem		
					CT321	Long-term surgical invasive				A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices				A0708	Power Problem		
					CT981	Single use				A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive				A0708	Power Problem		
1810	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1811	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1812	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1813	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1814	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1815	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1816	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	14/04/2016	
1817	2015				CT258	Implantable defibrillators				A0703	Along	14/04/2016	
1818	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1819	2015				CT258	Implantable defibrillators				A0708	Power Problem		
1820	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1821	2016	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices				A0709	Device Sensing Problem		
					CT1150	Defibrillators				A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices				A0709	Device Sensing Problem		
					CT145	Cardiovascular devices				A07	Electrical /Electronic Property Problem		
					CT233	Surgical				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		

					CT2406	Implantable				A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT2985	Active				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT981	Single use				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
1822	2016	TBD			CT258	implantable defibrillators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
1823	2015			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A11	Computer Software Problem		
										A1102	Application Program Problem		
1824	2015					CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1825	2016	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0708	General Electronic Property Problem	31/08/2016	
										A0708	Power Problem	31/08/2016	
1826	2015	All other reportable incidents				CT258	implantable defibrillators			A0704	Migration or Expulsion of Device		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1827	2016	Death		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1828	2015	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1829	2015			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1830	2015			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
										A0709	Device Sensing Problem		
1831	2015			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1832	2016	TBD				CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1833	2015	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem	04/11/2015	
										A0708	Power Problem	04/11/2015	
1834	2015			35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT1150	Defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT145	Cardiovascular devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT233	Surgical				A07	Electrical /Electronic Property Problem		
										A0708	Device Sensing Problem		
					CT2406	Implantable				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2407	Active implantable				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators				A07	Electrical /Electronic Property Problem		

					CT2985	Active				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT981	Single use				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive				A0709	Device Sensing Problem		
										A07	Device Sensing Problem		
1835	2015	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	25/11/2015	
										A0708	Power Problem	25/11/2015	
1836	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1837	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	19/08/2016	
										A0709	Device Sensing Problem		
1838	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	19/08/2016	
										A0708	Power Problem		
1839	2016	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT1150	Defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT145	Cardiovascular devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT233	Surgical				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2406	Implantable				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2407	Active implantable				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT2985	Active				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT3001	Implantable metal				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT3007	Implantable ceramic				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT314	Electrically powered				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT449	Generators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT981	Single use				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT983	Surgical invasive				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1840	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1841	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1842	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1843	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0703	Arrhythmia		
1844	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1845	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		

1846	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1847	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1848	2015	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1849	2015	All other reportable incidents			CT258	Implantable defibrillators				A0708	Power Problem		
1849	2015	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	01/06/2015	
1850	2015				CT258	Implantable defibrillators				A0708	Power Problem	01/06/2015	
1851	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1851	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
1852	2016	All other reportable incidents			CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1853	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1853	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1854	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A1304	Telemetry Discrepancy		
1855	2015	All other reportable incidents			CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1856	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1857	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1857	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1858	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	15/04/2016	
1858	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0703	Arding	15/04/2016	
1859	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1860	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1861	2016	All other reportable incidents			CT258	Implantable defibrillators				A0708	Power Problem		
1862	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	01/09/2016	
1863	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem	01/09/2016	
1864	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1864	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem	17/02/2016	
1865	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem	17/02/2016	
1866	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1866	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1866	2016	Death			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	27/04/2016	
1867	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem	27/04/2016	
1868	2015	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1869	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1870	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1871	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A09	Output Problem		
1872	2016	TBD			CT258	Implantable defibrillators				A090404	Output Above Specifications		
1873	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1874	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1875	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A09	Output Problem		
1876	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0907	No Device Output		
1877	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1878	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
1879	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A0708	Power Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A11	Computer Software Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A1102	Application Program Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT1147	Defibrillators and associated devices				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT1147	Defibrillators and associated devices				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT1150	Defibrillators				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT1150	Defibrillators				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT141	Electrodes/Leads and associated devices				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT141	Electrodes/Leads and associated devices				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT145	Cardiovascular devices				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT145	Cardiovascular devices				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT233	Surgical				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT233	Surgical				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT2406	Implantable				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT2406	Implantable				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT2407	Active implantable				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT2407	Active implantable				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices				A17	Compatibility Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT2726	Physiological monitoring/measuring devices				A01	Patient Device Interaction Problem		
1880	2015		35852	Single-chamber implantable defibrillator	CT2726	Physiological monitoring/measuring devices				A17	Compatibility Problem		

					CT2727	Active implant devices/ancillaries				A01	Patient Device Interaction Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators				A01	Patient Device Interaction Problem		
					CT2985	Active				A17	Compatibility Problem		
					CT3001	Implantable metal				A01	Patient Device Interaction Problem		
					CT3002	Implantable synthetic polymer				A17	Compatibility Problem		
					CT3006	Implantable inorganic material				A01	Patient Device Interaction Problem		
					CT3007	Implantable ceramic				A17	Compatibility Problem		
					CT314	Electrically powered				A01	Patient Device Interaction Problem		
					CT321	Long-term surgical invasive				A17	Compatibility Problem		
					CT449	Generators and associated devices				A01	Patient Device Interaction Problem		
					CT981	Single use				A17	Compatibility Problem		
					CT983	Surgical invasive				A01	Patient Device Interaction Problem		
1881	2016	TBD			CT258	Implantable defibrillators				A17	Compatibility Problem		
1882	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1883	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1884	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1885	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1886	2016	TBD			CT258	Implantable defibrillators				A11	Computer Software Problem		
1887	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A1102	Application Program Problem		
1888	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1889	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1890	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1891	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1892	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1893	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1894	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information	21/09/2016	
1895	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1896	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1897	2015				CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1898	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1899	2016	All other reportable incidents			CT258	Implantable defibrillators				A0708	Power Problem		
1900	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	03/11/2016	
1901	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem	03/11/2016	
1902	2015	All other reportable incidents			CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1903	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	15/06/2015	
1904	2015				CT258	Implantable defibrillators				A0708	Power Problem	15/06/2015	
1905	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1906	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1907	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1908	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1909	2016	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices				A0708	Power Problem		
					CT1150	Defibrillators				A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices				A0708	Power Problem		
										A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		

					CT145	Cardiovascular devices				A07	Electrical /Electronic Property Problem		
					CT233	Surgical				A0708	Power Problem		
										A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT2406	implantable				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT2407	Active implantable				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT263	Cardiographs and associated devices				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT2726	Physiological monitoring/measuring devices				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT2727	Active implant devices/ancillaries				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT2750	implantable cardiac electrical stimulators and associated devices				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT2866	Implantable cardiac electrical stimulators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT2985	Active				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT3001	Implantable metal				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT3002	Implantable synthetic polymer				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT3006	implantable inorganic material				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT3007	implantable ceramic				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT314	Electrically powered				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT321	Long-term surgical invasive				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT449	Generators and associated devices				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT981	Single use				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
					CT983	Surgical invasive				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1910	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	14/07/2015	
										A0708	Power Problem		
1911	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A09	Output Problem	14/07/2015	
										A090404	Output Above Specifications		
1912	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Device Sensing Problem		
1913	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem	03/05/2016	
										A26	Insufficient Device Problem Information	03/05/2016	
1914	2015	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	03/12/2015	
										A0708	Power Problem	03/12/2015	
1915	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1916	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	29/04/2016	
										A0703	Arding	29/04/2016	
1917	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1918	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1919	2015				CT258	implantable defibrillators				A13	Communication or Transmission Problem		
										A26	Insufficient Device Problem Information		
1920	2015				CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1921	2015				CT258	implantable defibrillators				A11	Computer Software Problem		
										A1102	Application Program Problem		
1922	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1923	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1924	2016	TBD			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1925	2015	Death			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1926	2015	All other reportable incidents			CT258	Implantable defibrillators				A1304	Telemetry Discrepancy	27/10/2015	
										A26	Insufficient Device Problem Information	27/10/2015	
1927	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	19/09/2016	
										A0708	Power Problem	19/09/2016	
1928	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1929	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1930	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1931	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1932	2016	All other reportable incidents			CT258	implantable defibrillators				A13	Communication or Transmission Problem	15/09/2016	
										A26	Insufficient Device Problem Information	15/09/2016	
1933	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1934	2016	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	18/05/2016	
										A0709	Device Sensing Problem	18/05/2016	

									A09	Output Problem	18/05/2016	
1935	2016	TBD			CT258	implantable defibrillators			A0907	No Device Output	18/05/2016	
									A07	Electrical /Electronic Property Problem		
1936	2015	All other reportable incidents			CT258	implantable defibrillators			A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
1937	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem	06/05/2016	
									A0708	Power Problem	06/05/2016	
1938	2015		36852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A12	Connection Problem		
									A1208	Fitting Problem		
					CT1147	Defibrillators and associated devices			A12	Connection Problem		
									A1208	Fitting Problem		
					CT1150	Defibrillators			A12	Connection Problem		
									A1208	Fitting Problem		
					CT141	Electrodes/Leads and associated devices			A12	Connection Problem		
									A1208	Fitting Problem		
					CT145	Cardiovascular devices			A12	Connection Problem		
									A1208	Fitting Problem		
					CT233	Surgical			A1208	Connection Problem		
									A12	Fitting Problem		
					CT2406	Implantable			A1208	Connection Problem		
									A12	Fitting Problem		
					CT2407	Active implantable			A1208	Connection Problem		
									A12	Fitting Problem		
					CT258	Implantable defibrillators			A1208	Connection Problem		
									A12	Fitting Problem		
					CT263	Cardiographs and associated devices			A1208	Connection Problem		
									A12	Fitting Problem		
					CT2726	Physiological monitoring/measuring devices			A1208	Connection Problem		
									A12	Fitting Problem		
					CT2727	Active implant devices/ancillaries			A1208	Connection Problem		
									A12	Fitting Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices			A1208	Connection Problem		
									A12	Fitting Problem		
					CT2866	Implantable cardiac electrical stimulators			A1208	Connection Problem		
									A12	Fitting Problem		
					CT2965	Active			A1208	Connection Problem		
									A12	Fitting Problem		
					CT3001	implantable metal			A1208	Connection Problem		
									A12	Fitting Problem		
					CT3002	implantable synthetic polymer			A1208	Connection Problem		
									A12	Fitting Problem		
					CT3006	implantable inorganic material			A1208	Connection Problem		
									A12	Fitting Problem		
					CT3007	Implantable ceramic			A1208	Connection Problem		
									A12	Fitting Problem		
					CT314	Electrically powered			A1208	Connection Problem		
									A12	Fitting Problem		
					CT321	Long-term surgical invasive			A1208	Connection Problem		
									A12	Fitting Problem		
					CT449	Generators and associated devices			A1208	Connection Problem		
									A12	Fitting Problem		
					CT981	Single use			A1208	Connection Problem		
									A12	Fitting Problem		
					CT983	Surgical invasive			A1208	Connection Problem		
									A12	Fitting Problem		
1939	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1940	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A16	Protective Measures Problem		
									A1602	Fail-Safe Problem		
1941	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1942	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1943	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1944	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1945	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1946	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1947	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1948	2015				CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1949	2016	All other reportable incidents			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	23/09/2016	
									A0708	Power Problem	23/09/2016	
1950	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
1951	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A26	Insufficient Device Problem Information		
1952	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
1953	2016	All other reportable incidents			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
1954	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		

1955	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1956	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1957	2015				CT258	Implantable defibrillators				A09	Output Problem		
1958	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0907	No Device Output		
1959	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1960	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1961	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1962	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1963	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1964	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0703	Arcing	16/05/2016	
1965	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1966	2016	All other reportable incidents			CT258	Implantable defibrillators				A0721	Circuit Failure	31/01/2016	
1967	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1968	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1969	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1970	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
1971	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
1972	2016	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A0708	Power Problem		
					CT1147	Defibrillators and associated devices				A01	Patient Device Interaction Problem	20/05/2016	
					CT1150	Defibrillators				A17	Compatibility Problem	20/05/2016	
					CT141	Electrodes/Leads and associated devices				A01	Patient Device Interaction Problem	20/05/2016	
					CT145	Cardiovascular devices				A17	Compatibility Problem	20/05/2016	
					CT233	Surgical				A01	Patient Device Interaction Problem	20/05/2016	
					CT2406	Implantable				A17	Compatibility Problem	20/05/2016	
					CT2407	Active implantable				A01	Patient Device Interaction Problem	20/05/2016	
					CT258	Implantable defibrillators				A17	Compatibility Problem	20/05/2016	
					CT263	Cardiographs and associated devices				A01	Patient Device Interaction Problem	20/05/2016	
					CT2726	Physiological monitoring/measuring devices				A17	Compatibility Problem	20/05/2016	
					CT2727	Active implant devices/ancillaries				A01	Patient Device Interaction Problem	20/05/2016	
					CT2750	Implantable cardiac electrical stimulators and associated devices				A17	Compatibility Problem	20/05/2016	
					CT2866	Implantable cardiac electrical stimulators				A01	Patient Device Interaction Problem	20/05/2016	
					CT2985	Active				A17	Compatibility Problem	20/05/2016	
					CT3001	Implantable metal				A01	Patient Device Interaction Problem	20/05/2016	
					CT3002	Implantable synthetic polymer				A17	Compatibility Problem	20/05/2016	
					CT3006	Implantable inorganic material				A01	Patient Device Interaction Problem	20/05/2016	
					CT3007	Implantable ceramic				A17	Compatibility Problem	20/05/2016	
					CT314	Electrically powered				A01	Patient Device Interaction Problem	20/05/2016	
					CT321	Long-term surgical invasive				A17	Compatibility Problem	20/05/2016	
					CT449	Generators and associated devices				A01	Patient Device Interaction Problem	20/05/2016	
					CT981	Single use				A17	Compatibility Problem	20/05/2016	
					CT983	Surgical invasive				A01	Patient Device Interaction Problem	20/05/2016	
1973	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A17	Compatibility Problem	20/05/2016	
1974	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1975	2016	All other reportable incidents			CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
										A07	Electrical /Electronic Property Problem	17/12/2015	

1976	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem	17/12/2015	
1977	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
1978	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
1979	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
1980	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
1981	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
										A07	Electrical /Electronic Property Problem		
1982	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem		
										A07	Electrical /Electronic Property Problem		
1983	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A13	Communication or Transmission Problem	03/05/2016	
										A26	Insufficient Device Problem Information	03/05/2016	
1984	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	15/12/2015	
										A0708	Power Problem	15/12/2015	
1985	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A1104	Computer Operating System Problem	15/12/2015	
										A26	Insufficient Device Problem Information		
1986	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A11	Computer Software Problem		
										A1102	Application Program Problem		
1987	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
1988	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1989	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A1104	Computer Operating System Problem		
1990	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1991	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem		
										A26	Insufficient Device Problem Information		
1992	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
1993	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1994	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1995	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
1996	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	09/12/2015	
										A0708	Power Problem	28/12/2015	
1997	2016	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	28/08/2016	
										A0708	Power Problem	28/08/2016	
1998	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
1999	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	04/10/2016	
										A0708	Power Problem	04/10/2016	
2000	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
2001	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2002	2015				CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2003	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2004	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem	18/12/2015	
										A26	Insufficient Device Problem Information	18/12/2015	
2005	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
2006	2016	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2007	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	14/10/2016	
										A0708	Power Problem	14/10/2016	
2008	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2009	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2010	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2011	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	10/10/2016	
										A0708	Power Problem	10/10/2016	
2012	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2013	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2014	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2015	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2016	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	24/10/2016	
										A0708	Power Problem	24/10/2016	
2017	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	25/10/2016	
										A0708	Power Problem	25/10/2016	
2018	2016		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A11	Computer Software Problem		
										A1102	Application Program Problem		
2019	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem		

									A26	Insufficient Device Problem Information		
2020	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2021	2016	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A01	Patient Device Interaction Problem		
					CT1147	Defibrillators and associated devices			A17	Compatibility Problem		
					CT1150	Defibrillators			A17	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT145	Cardiovascular devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT233	Surgical			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2406	Implantable			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2407	Active implantable			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT258	Implantable defibrillators			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT263	Cardiographs and associated devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2727	Active implant devices/ancillaries			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2985	Active			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3001	Implantable metal			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3006	Implantable inorganic material			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3007	Implantable ceramic			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT314	Electrically powered			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT321	Long-term surgical invasive			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT449	Generators and associated devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT981	Single use			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT983	Surgical invasive			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
2022	2016	TBD			CT258	Implantable defibrillators			A13	Communication or Transmission Problem		
									A26	Insufficient Device Problem Information		
2023	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	16/12/2015	
									A0708	Power Problem	16/12/2015	
2024	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2025	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	10/10/2016	
									A0708	Power Problem	10/10/2016	
2026	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2027	2016	TBD			CT258	Implantable defibrillators			A05	Mechanical Problem		
									A0512	Unintended Movement		
2028	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2029	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2030	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT1147	Defibrillators and associated devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT1150	Defibrillators			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT145	Cardiovascular devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT233	Surgical			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2406	Implantable			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2407	Active implantable			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT258	Implantable defibrillators			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT263	Cardiographs and associated devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices			A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		

					CT2727	Active implant devices/ancillaries				A01	Patient Device Interaction Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators				A01	Patient Device Interaction Problem		
					CT2985	Active				A17	Compatibility Problem		
					CT3001	Implantable metal				A01	Patient Device Interaction Problem		
					CT3002	Implantable synthetic polymer				A17	Compatibility Problem		
					CT3006	Implantable inorganic material				A01	Patient Device Interaction Problem		
					CT3007	Implantable ceramic				A17	Compatibility Problem		
					CT314	Electrically powered				A01	Patient Device Interaction Problem		
					CT321	Long-term surgical invasive				A17	Compatibility Problem		
					CT449	Generators and associated devices				A01	Patient Device Interaction Problem		
					CT981	Single use				A17	Compatibility Problem		
					CT983	Surgical invasive				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
2031	2015			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2032	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	13/10/2016	
2033	2015				CT258	Implantable defibrillators				A0708	Power Problem	13/10/2016	
2034	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
2035	2016	Death		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
2036	2016	All other reportable incidents			CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2037	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
2038	2016	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0709	Device Sensing Problem		
2039	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	14/10/2016	
2040	2016	All other reportable incidents			CT258	Implantable defibrillators				A0708	Power Problem	14/10/2016	
2041	2015			47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	19/10/2016	
2042	2016	TBD		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem	02/06/2016	
2043	2016	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	02/06/2016	
2044	2016	TBD		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0709	Device Sensing Problem	02/06/2016	
2045	2016	All other reportable incidents		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	19/05/2016	
2046	2016	TBD		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem	19/05/2016	
2047	2015			35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A26	Insufficient Device Problem Information		
					CT1147	Defibrillators and associated devices				A07	Electrical /Electronic Property Problem	12/11/2016	
					CT1150	Defibrillators				A0708	Power Problem	12/11/2016	
					CT141	Electrodes/Leads and associated devices				A07	Electrical /Electronic Property Problem	03/11/2016	
					CT145	Cardiovascular devices				A0708	Power Problem	03/11/2016	
					CT233	Surgical				A09	Output Problem		
					CT2406	Implantable				A090404	Output Above Specifications		
					CT2407	Active implantable				A07	Electrical /Electronic Property Problem	31/12/2015	
					CT258	Implantable defibrillators				A0708	Power Problem	31/12/2015	
					CT263	Cardiographs and associated devices				A01	Patient Device Interaction Problem	04/11/2016	
					CT2726	Physiological monitoring/measuring devices				A17	Compatibility Problem	04/11/2016	
					CT2727	Active implant devices/ancillaries				A07	Electrical /Electronic Property Problem	27/08/2015	
					CT2750	Implantable cardiac electrical stimulators and associated devices				A0708	Power Problem	27/08/2015	
					CT2866	Implantable cardiac electrical stimulators				A07	Electrical /Electronic Property Problem	27/08/2015	
					CT2985	Active				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
										A0708	Power Problem	27/08/2015	

					CT3001	Implantable metal				A07	Electrical /Electronic Property Problem	27/08/2015	
					CT3002	Implantable synthetic polymer				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
					CT3006	Implantable inorganic material				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
					CT3007	Implantable ceramic				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
					CT314	Electrically powered				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
					CT321	Long-term surgical invasive				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
					CT449	Generators and associated devices				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
					CT981	Single use				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
					CT983	Surgical invasive				A0708	Power Problem	27/08/2015	
										A07	Electrical /Electronic Property Problem	27/08/2015	
2048	2016	Death			CT258	Implantable defibrillators				A0709	Device Sensing Problem		
2049	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2050	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	16/10/2016	
										A0708	Power Problem	16/10/2016	
2051	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2052	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2053	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2054	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2055	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2056	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2057	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A1304	Telemetry Discrepancy	18/08/2015	
										A26	Insufficient Device Problem Information	18/08/2015	
2058	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2059	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2060	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2061	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2062	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2063	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
										A07	Electrical /Electronic Property Problem		
2064	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem	14/11/2016	
2065	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem	14/11/2016	
										A13	Communication or Transmission Problem		
2066	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
										A07	Electrical /Electronic Property Problem		
2067	2015				CT258	Implantable defibrillators				A0708	Power Problem		
										A07	Electrical /Electronic Property Problem		
2068	2015				CT258	Implantable defibrillators				A0708	Power Problem		
										A07	Electrical /Electronic Property Problem		
2069	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
2070	2016	All other reportable incidents			CT258	Implantable defibrillators				A0708	Power Problem	19/10/2016	
										A0708	Power Problem	19/10/2016	
2071	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2072	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT1147	Defibrillators and associated devices				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT1150	Defibrillators				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT145	Cardiovascular devices				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT233	Surgical				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT2406	Implantable				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT2407	Active implantable				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT258	Implantable defibrillators				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT263	Cardiographs and associated devices				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
					CT2727	Active implant devices/ancillaries				A01	Patient Device Interaction Problem		

					CT2750	Implantable cardiac electrical stimulators and associated devices				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT2866	Implantable cardiac electrical stimulators				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT2985	Active				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT3001	Implantable metal				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT3002	Implantable synthetic polymer				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT3006	Implantable inorganic material				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT3007	Implantable ceramic				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT314	Electrically powered				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT321	Long-term surgical invasive				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT449	Generators and associated devices				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT981	Single use				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
					CT983	Surgical invasive				A17	Compatibility Problem		
										A01	Patient Device Interaction Problem		
2073	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2074	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
2075	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
2076	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2077	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	17/08/2015	
										A0708	Power Problem	17/08/2015	
2078	2015	All other reportable incidents			CT258	Implantable defibrillators				A1304	Telemetry Discrepancy	04/09/2015	
2079	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information	04/09/2015	
2080	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2081	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	08/07/2015	
										A0708	Power Problem	08/07/2015	
										A26	Insufficient Device Problem Information	08/07/2015	
2082	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2083	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT1150	Defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT145	Cardiovascular devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT233	Surgical				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT2406	Implantable				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT2407	Active implantable				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
										A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		

					CT2727	Active implant devices/ancillaries				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT2806	Implantable cardiac electrical stimulators				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT2985	Active				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT3001	Implantable metal				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT3002	Implantable synthetic polymer				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT3006	Implantable inorganic material				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT3007	Implantable ceramic				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT314	Electrically powered				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT321	Long-term surgical invasive				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT449	Generators and associated devices				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT981	Single use				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
					CT983	Surgical invasive				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
2084	2015	All other reportable incidents			CT258	Implantable defibrillators				A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem	03/11/2016	
2085	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem	03/11/2016	
2086	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2087	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A16	Protective Measures Problem	06/06/2016	
										A1802	Fail-Safe Problem	06/06/2016	
2088	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem		
										A26	Insufficient Device Problem Information		
2089	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2090	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem		
										A26	Insufficient Device Problem Information		
2091	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2092	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2093	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A17	Compatibility Problem		
2094	2015				CT258	Implantable defibrillators				A1702	Device-Device Incompatibility		
										A07	Electrical /Electronic Property Problem		
2095	2015				CT258	Implantable defibrillators				A0708	Power Problem		
										A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2096	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	17/10/2016	
										A0708	Power Problem	17/10/2016	
2097	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2098	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2099	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	04/11/2016	
										A0708	Power Problem	04/11/2016	
										A26	Insufficient Device Problem Information	04/11/2016	
2100	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2101	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		

2102	2015	All other reportable incidents			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2103	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2104	2016	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A24	No Apparent Device Problem		
									A26	Insufficient Device Problem Information		
2105	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators			A07	Electrical /Electronic Property Problem	10/03/2016	
									A0708	Power Problem	10/03/2016	
2106	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	09/09/2015	
									A0708	Power Problem	09/09/2015	
2107	2015				CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2108	2016	TBD			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2109	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2110	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2111	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators						
2112	2016	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
									A09	Output Problem		
2113	2015				CT258	Implantable defibrillators			A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
2114	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0709	Device Sensing Problem		
									A26	Insufficient Device Problem Information		
2115	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2116	2016	TBD			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2117	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2118	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2119	2016	All other reportable incidents			CT258	implantable defibrillators			A13	Communication or Transmission Problem		
									A26	Insufficient Device Problem Information		
2120	2015				CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2121	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2122	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2123	2016	All other reportable incidents			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	01/02/2016	
									A0708	Power Problem	01/02/2016	
2124	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2125	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem	02/10/2016	
									A0708	Power Problem	02/10/2016	
2126	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2127	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2128	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A11	Computer Software Problem		
									A1102	Application Program Problem		
2129	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2130	2015				CT258	implantable defibrillators			A09	Output Problem		
									A090404	Output Above Specifications		
2131	2015				CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2132	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A09	Output Problem		
									A0907	No Device Output		
2133	2016	TBD			CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2134	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2135	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2136	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators						
									A26	Insufficient Device Problem Information		
2137	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2138	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2139	2016	TBD			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2140	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A12	Connection Problem	25/09/2015	
									A1204	Failure to Disconnect	25/09/2015	
					CT1147	Defibrillators and associated devices			A12	Connection Problem	25/09/2015	
									A1204	Failure to Disconnect	25/09/2015	
					CT1150	Defibrillators			A12	Connection Problem	25/09/2015	
									A1204	Failure to Disconnect	25/09/2015	
					CT141	Electrodes/Leads and associated devices			A12	Connection Problem	25/09/2015	
									A1204	Failure to Disconnect	25/09/2015	
					CT145	Cardiovascular devices			A12	Connection Problem	25/09/2015	
									A1204	Failure to Disconnect	25/09/2015	
					CT233	Surgical			A12	Connection Problem	25/09/2015	
									A1204	Failure to Disconnect	25/09/2015	
					CT2406	Implantable			A12	Connection Problem	25/09/2015	
									A1204	Failure to Disconnect	25/09/2015	
					CT2407	Active implantable			A12	Connection Problem	25/09/2015	
									A1204	Failure to Disconnect	25/09/2015	

					CT258	Implantable defibrillators				A12	Connection Problem	25/09/2015	
					CT263	Cardiographs and associated devices				A1204	Failure to Disconnect	25/09/2015	
										A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT2726	Physiological monitoring/measuring devices				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT2727	Active implant devices/incillaries				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT2750	Implantable cardiac electrical stimulators and associated devices				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT2866	Implantable cardiac electrical stimulators				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT2985	Active				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT3001	Implantable metal				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT3002	implantable synthetic polymer				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT3006	Implantable inorganic material				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT3007	Implantable ceramic				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT314	Electrically powered				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT321	Long-term surgical invasive				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT449	Generators and associated devices				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT981	Single use				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
					CT983	Surgical invasive				A12	Connection Problem	25/09/2015	
										A1204	Failure to Disconnect	25/09/2015	
2141	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2142	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2143	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2144	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2145	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	19/11/2016	
										A0708	Power Problem	19/11/2016	
2146	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2147	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	10/11/2016	
										A0708	Power Problem	10/11/2016	
2148	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	17/02/2016	
										A0708	Power Problem	17/02/2016	
2149	2015				CT258	Implantable defibrillators				A0104	Migration or Expulsion of Device		
2150	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2151	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2152	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2153	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2154	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2155	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	19/11/2016	
										A0708	Power Problem	19/11/2016	
2156	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	04/11/2016	
										A0708	Power Problem	04/11/2016	
2157	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2158	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2159	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2160	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	17/10/2016	
										A0708	Power Problem	17/10/2016	
2161	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	19/11/2016	
										A0708	Power Problem	19/11/2016	
2162	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	20/11/2016	
										A0709	Device Sensing Problem	20/11/2016	
2163	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2164	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2165	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	12/10/2016	
										A0708	Power Problem	12/10/2016	
2166	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Patient Device Interaction Problem		
										A17	Compatibility Problem		
2167	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A01	Patient Device Interaction Problem		
										A17	Compatibility Problem		
2168	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2169	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		

2170	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	18/11/2016	
2171	2015	Death			CT258	Implantable defibrillators				A0708	Power Problem	18/11/2016	
2172	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A16	Protective Measures Problem		
2173	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A1602	Fail-Safe Problem		
2174	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	12/11/2016	
2175	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Electrical /Electronic Property Problem	12/11/2016	
2176	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Power Problem	14/11/2016	
2177	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Electrical /Electronic Property Problem	14/11/2016	
2178	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2179	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
2180	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
2181	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	13/12/2016	
2182	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Power Problem	13/12/2016	
2183	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
2184	2016	All other reportable incidents			CT258	Implantable defibrillators				A0708	Electrical /Electronic Property Problem		
2185	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Power Problem		
2186	2016	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Electrical /Electronic Property Problem	18/11/2016	
2187	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Power Problem		
2188	2015	Death			CT258	Implantable defibrillators				A0709	Device Sensing Problem		
2189	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices				A0708	Power Problem	27/09/2015	
					CT1150	Defibrillators				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT141	Electrodes/Leads end associated devices				A0708	Power Problem	27/09/2015	
					CT145	Cardiovascular devices				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT233	Surgical				A0708	Power Problem	27/09/2015	
					CT2406	Implantable				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT2407	Active implantable				A0708	Power Problem	27/09/2015	
					CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT263	Cardiographs and associated devices				A0708	Power Problem	27/09/2015	
					CT2726	Physiological monitoring/measuring devices				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT2727	Active implant devices/ancillaries				A0708	Power Problem	27/09/2015	
					CT2750	Implantable cardiac electrical stimulators and associated devices				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT2866	Implantable cardiac electrical stimulators				A0708	Power Problem	27/09/2015	
					CT2985	Active				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT3001	Implantable metal				A0708	Power Problem	27/09/2015	
					CT3002	Implantable synthetic polymer				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT3006	Implantable inorganic material				A0708	Power Problem	27/09/2015	
					CT3007	Implantable ceramic				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT314	Electrically powered				A0708	Power Problem	27/09/2015	
					CT321	Long-term surgical invasive				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT449	Generators and associated devices				A0708	Power Problem	27/09/2015	
					CT981	Single use				A07	Electrical /Electronic Property Problem	27/09/2015	
					CT983	Surgical invasive				A0708	Power Problem	27/09/2015	
2190	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
2191	2015				CT258	Implantable defibrillators				A0709	Device Sensing Problem		
2192	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0708	Electrical /Electronic Property Problem		
										A07	Power Problem		

2193	2016	TBD			CT258	Implantable defibrillators				A0708	Power Problem		
										A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2194	2016	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A09	Output Problem		
					CT1147	Defibrillators and associated devices				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT141	Electrodes/Leads and associated devices				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT145	Cardiovascular devices				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT233	Surgical				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2407	Active implantable				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2726	Physiological monitoring/measuring devices				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2727	Active implant devices/ancillaries				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3001	Implantable metal				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3002	implantable synthetic polymer				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3006	implantable inorganic material				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3007	Implantable ceramic				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT314	Electrically powered				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT321	Long-term surgical invasive				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT449	Generators and associated devices				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT981	Single use				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT983	Surgical invasive				A09	Output Problem		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
2195	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	25/10/2016	
										A0708	Power Problem	25/10/2016	
2196	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	15/11/2016	
										A0708	Power Problem	15/11/2016	
										A26	Insufficient Device Problem Information	15/11/2016	
2197	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	21/10/2016	
										A0708	Power Problem	21/10/2016	
2198	2016	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	01/12/2016	
										A0708	Power Problem	01/12/2016	
2199	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2200	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	11/11/2016	
										A0708	Power Problem	11/11/2016	
2201	2016	All other reportable incidents			CT258	Implantable defibrillators				A24	No Apparent Device Problem		
										A26	Insufficient Device Problem Information		
2202	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A16	Protective Measures Problem		
										A1601	Device Alarm System		
2203	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	18/10/2016	
										A0708	Power Problem	18/10/2016	
2204	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	18/11/2016	
										A0708	Power Problem	18/11/2016	
2205	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	07/11/2016	
										A0708	Power Problem	07/11/2016	
2206	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2207	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	29/10/2016	
										A0708	Power Problem	29/10/2016	
2208	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	01/11/2016	
										A0708	Power Problem	01/11/2016	
2209	2016	All other reportable incidents			CT258	Implantable defibrillators				A01	Patient Device Interaction Problem	18/11/2016	
										A17	Compatibility Problem	18/11/2016	
2210	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A16	Protective Measures Problem		
										A1602	Fail-Safe Problem		
2211	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2212	2015	All other reportable incidents			CT258	Implantable defibrillators				A16	Protective Measures Problem		
										A1602	Fail-Safe Problem		
2213	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	26/11/2015	

2214	2016	All other reportable incidents			CT258	implantable defibrillators				A0708	Power Problem	20/11/2015	
2215	2015	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
2216	2016	All other reportable incidents			CT258	implantable defibrillators				A0708	Power Problem		
2217	2016	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	29/10/2016	
2218	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem	01/12/2016	
2219	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	29/10/2016	
2220	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem	29/10/2016	
2221	2016	All other reportable incidents			CT258	implantable defibrillators				A24	No Apparent Device Problem	29/11/2016	
2222	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information	29/11/2016	
2223	2016	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
2224	2016	All other reportable incidents			CT258	implantable defibrillators				A0708	Power Problem		
2225	2016	All other reportable incidents			CT258	implantable defibrillators				A24	No Apparent Device Problem		
2226	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
2227	2016	All other reportable incidents			CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	29/10/2016	
2228	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem	29/10/2016	
2229	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information	29/10/2016	
2230	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	10/11/2016	
2231	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem	10/11/2016	
2232	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A26	Insufficient Device Problem Information		
2233	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem	30/11/2016	
2234	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A0708	Power Problem	30/11/2016	
2235	2016	All other reportable incidents			CT258	implantable defibrillators				A26	Insufficient Device Problem Information	30/11/2016	
2236	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators				A07	Electrical /Electronic Property Problem		
2237	2016	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices				A0708	Power Problem		
					CT1147	Defibrillators and associated devices				A07	Electrical /Electronic Property Problem	05/12/2016	
					CT1150	Defibrillators				A0708	Power Problem	05/12/2016	
					CT141	Electrodes/Leads and associated devices				A07	Electrical /Electronic Property Problem	31/10/2016	
					CT145	Cardiovascular devices				A0708	Power Problem	31/10/2016	
					CT233	Surgical				A07	Electrical /Electronic Property Problem	30/11/2016	
					CT2406	Implantable				A0708	Power Problem	30/11/2016	
					CT2407	Active implantable				A07	Electrical /Electronic Property Problem	30/11/2016	
					CT258	Implantable defibrillators				A0708	Power Problem	30/11/2016	
					CT263	Cardiographs and associated devices				A07	Electrical /Electronic Property Problem	30/11/2016	
					CT2726	Physiological monitoring/measuring devices				A0708	Power Problem	30/11/2016	
					CT2727	Active implant devices/ancillaries				A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices				A0708	Power Problem		
					CT2866	Implantable cardiac electrical stimulators				A07	Electrical /Electronic Property Problem		
					CT2985	Active				A0708	Power Problem		
					CT3001	Implantable metal				A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer				A0708	Power Problem		
					CT3006	Implantable inorganic material				A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic				A0708	Power Problem		
					CT314	Electrically powered				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		

					CT321	Long-term surgical invasive				A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT981	Single use				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
2238	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
2239	2016	All other reportable incidents			CT258	Implantable defibrillators				A0709	Device Sensing Problem		
										A26	Insufficient Device Problem Information	15/11/2016	
2240	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
2241	2016	All other reportable incidents			CT258	Implantable defibrillators				A0708	Power Problem		
2242	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2243	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2244	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2245	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2246	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2247	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2248	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	12/12/2016	
										A0708	Power Problem	12/12/2016	
2249	2016	All other reportable incidents			CT258	Implantable defibrillators				A13	Communication or Transmission Problem	22/08/2016	
										A16	Protective Measures Problem	22/08/2016	
										A1602	Fail-Safe Problem	22/08/2016	
										A26	Insufficient Device Problem Information	22/08/2016	
2250	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	29/10/2016	
										A0708	Power Problem	29/10/2016	
2251	2016	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	14/11/2016	
										A0708	Power Problem	14/11/2016	
2252	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2253	2015				CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2254	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2255	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2256	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2257	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2258	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2259	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2260	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	29/11/2016	
										A0708	Power Problem	29/11/2016	
2261	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A13	Communication or Transmission Problem	22/09/2015	
										A26	Insufficient Device Problem Information	22/09/2015	
2262	2015	All other reportable incidents			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2263	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	18/09/2015	
										A0708	Power Problem	18/09/2015	
2264	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2265	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2266	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2267	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A26	Insufficient Device Problem Information		
2268	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2269	2016	TBD			CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2270	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A16	Protective Measures Problem	09/10/2015	
										A1602	Fail-Safe Problem	09/10/2015	
2271	2016	TBD			CT258	Implantable defibrillators				A09	Output Problem		
										A090404	Output Above Specifications		
2272	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2273	2016	All other reportable incidents			CT258	Implantable defibrillators				A26	Insufficient Device Problem Information	19/11/2016	
2274	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem	19/11/2016	
										A0708	Power Problem	19/11/2016	
2275	2016	All other reportable incidents			CT258	Implantable defibrillators				A24	No Apparent Device Problem	19/11/2016	
										A26	Insufficient Device Problem Information	19/11/2016	
2276	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators				A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2277	2015	All other reportable incidents			CT258	Implantable defibrillators				A1304	Telemetry Discrepancy		
										A16	Protective Measures Problem		
										A1602	Fail-Safe Problem		
										A26	Insufficient Device Problem Information		

2278	2016	TBD			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2279	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
2280	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information		
2281	2016	TBD			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2282	2016	TBD			CT258	Implantable defibrillators			A0708	Power Problem		
2283	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2284	2016	TBD			CT258	Implantable defibrillators			A0708	Power Problem		
2285	2016	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2286	2015	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
2287	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	26/02/2016	
2288	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2289	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
2290	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A1104	Computer Operating System Problem		
2291	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2292	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
2293	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2294	2016	All other reportable incidents			CT258	Implantable defibrillators			A0708	Power Problem		
2295	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A24	No Apparent Device Problem	11/11/2016	
2296	2016	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	11/11/2016	
2297	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	27/02/2018	
2298	2018	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	27/02/2018	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2299	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/06/2018	
									A0709	Device Sensing Problem	14/06/2018	

2300	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2301	2015		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
2302	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	06/04/2018	
2303	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	06/04/2018	
2304	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem		
2305	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
2306	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	21/02/2018	
2307	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	21/02/2018	
2308	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A16	Protective Measures Problem		
2309	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1602	Fail-Safe Problem		
2310	2018	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2311	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
2312	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/12/2016	
2313	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	08/12/2016	
2314	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	01/12/2016	
2315	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	01/12/2016	
2316	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/12/2016	
2317	2015		35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	06/12/2016	
2318	2015		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2319	2015		35852	Single-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A0708	Power Problem		
2320	2015		35852	Single-chamber implantable defibrillator	CT1150	Defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2321	2015		35852	Single-chamber implantable defibrillator	CT1150	Defibrillators	E2401	Insufficient Information	A0708	Power Problem		
2322	2015		35852	Single-chamber implantable defibrillator	CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2323	2015		35852	Single-chamber implantable defibrillator	CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A0708	Power Problem		
2324	2015		35852	Single-chamber implantable defibrillator	CT145	Cardiovascular devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2325	2015		35852	Single-chamber implantable defibrillator	CT145	Cardiovascular devices	E2401	Insufficient Information	A0708	Power Problem		
2326	2015		35852	Single-chamber implantable defibrillator	CT233	Surgical	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2327	2015		35852	Single-chamber implantable defibrillator	CT233	Surgical	E2401	Insufficient Information	A0708	Power Problem		
2328	2015		35852	Single-chamber implantable defibrillator	CT2406	Implantable	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2329	2015		35852	Single-chamber implantable defibrillator	CT2406	Implantable	E2401	Insufficient Information	A0708	Power Problem		
2330	2015		35852	Single-chamber implantable defibrillator	CT2407	Active implantable	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2331	2015		35852	Single-chamber implantable defibrillator	CT2407	Active implantable	E2401	Insufficient Information	A0708	Power Problem		
2332	2015		35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2333	2015		35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A0708	Power Problem		
2334	2015		35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2335	2015		35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2401	Insufficient Information	A0708	Power Problem		
2336	2015		35852	Single-chamber implantable defibrillator	CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2337	2015		35852	Single-chamber implantable defibrillator	CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A0708	Power Problem		
2338	2015		35852	Single-chamber implantable defibrillator	CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2339	2015		35852	Single-chamber implantable defibrillator	CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A0708	Power Problem		
2340	2015		35852	Single-chamber implantable defibrillator	CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2341	2015		35852	Single-chamber implantable defibrillator	CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A0708	Power Problem		
2342	2015		35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2343	2015		35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A0708	Power Problem		
2344	2015		35852	Single-chamber implantable defibrillator	CT2985	Active	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2345	2015		35852	Single-chamber implantable defibrillator	CT2985	Active	E2401	Insufficient Information	A0708	Power Problem		
2346	2015		35852	Single-chamber implantable defibrillator	CT3001	Implantable metal	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2347	2015		35852	Single-chamber implantable defibrillator	CT3001	Implantable metal	E2401	Insufficient Information	A0708	Power Problem		

					CT3002	Implantable synthetic polymer			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
					CT981	Single use			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
2318	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	14/12/2016	
2319	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	14/12/2016	
2320	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/12/2016	
2321	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	20/12/2016	
2322	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	17/12/2016	
2323	2015				CT258	Implantable defibrillators			A0708	Power Problem	17/12/2016	
2324	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	15/12/2016	
2325	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	15/12/2016	
2326	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	12/12/2016	
2327	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	12/12/2016	
2328	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem	10/12/2016	
2329	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	10/12/2016	
2330	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/07/2018	
2331	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	08/12/2016	
2332	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	31/10/2016	
2333	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	09/12/2016	
2334	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	09/12/2016	
2335	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	09/12/2016	
2336	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	09/12/2016	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A0907	No Device Output		

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
2337	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2338	2016	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem	23/11/2016	
2339	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F10	inadequate/inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information	23/11/2016	
2340	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/10/2016	
2341	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	23/10/2016	
2342	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	23/10/2016	
2343	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
2344	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2345	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
2346	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2347	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	13/12/2016	
2348	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/12/2016	
2349	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	09/12/2016	
2350	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	09/12/2016	
2351	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem	12/12/2016	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	12/12/2016	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT3008	implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT3007	implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/12/2016	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/12/2016	
2352	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2353	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2354	2017	All other reportable incidents			CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
2355	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2356	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT133	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
2357	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2358	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/12/2016	
									A0708	Power Problem	13/12/2016	
2359	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/12/2016	
									A0708	Power Problem	23/12/2016	
2360	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	05/01/2017	
									A0708	Power Problem	05/01/2017	
2361	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/06/2018	
									A0709	Device Sensing Problem	14/06/2018	
							F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/06/2018	
									A0709	Device Sensing Problem	14/06/2018	
2362	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A04	Material Integrity Problem	02/07/2018	
									A0413	Material Separation	02/07/2018	
2363	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2364	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2365	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem		
									A26	Insufficient Device Problem Information		
2366	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/12/2016	
									A0708	Power Problem	07/12/2016	
2367	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2368	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2369	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2370	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2371	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic	A09	Output Problem		

						CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT263	Cardiographs end associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
2372	2017	TBD				CT258	Implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
								F1905	Device Revision or Replacement	A17	Compatibility Problem		
2373	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
2374	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
2375	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/01/2017		
2376	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	06/01/2017		
2377	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	01/08/2018		
2378	2018	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018		
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018		
					CT1150	Defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018		
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018		
					CT145	Cardiovascular devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018		
					CT233	Surgical	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018		
					CT2406	Implantable	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018		
					CT2407	Active implantable	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018		
					CT258	Implantable defibrillators	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018		
					CT263	Cardiographs and associated devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018		
					CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018		
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018		
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018		

					CT2985	Active	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
					CT3001	Implantable metal	E2401	Insufficient Information	A0709	Device Sensing Problem	01/08/2018	
									A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
					CT3006	Implantable inorganic material	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
					CT3007	Implantable ceramic	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
					CT314	Electrically powered	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
					CT449	Generators and associated devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
					CT981	Single use	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
					CT983	Surgical invasive	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0709	Device Sensing Problem	01/08/2018	
2379	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/07/2018	
									A0709	Device Sensing Problem	25/07/2018	
2380	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT233	Surgical	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT2406	Implantable	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT2985	Active	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT981	Single use	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
2381	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2382	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
2383	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	09/01/2017	
									A0708	Power Problem	09/01/2017	
2384	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	11/10/2017	
									A0708	Power Problem	11/10/2017	
2385	2018	All other reportable incidents			CT258	Implantable defibrillators	F1001	Absence of Treatment	A07	Electrical /Electronic Property Problem	08/03/2018	
									A07	Power Problem	08/03/2018	
2386	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2387	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/07/2018	
									A0708	Power Problem	20/07/2018	
2388	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	17/08/2018	
									A0708	Power Problem	17/08/2018	
2389	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/03/2018	
									A0708	Power Problem	07/03/2018	
2390	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	11/12/2016	

								A0708	Power Problem	11/12/2016	
2391	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
									A0708	Power Problem	
2392	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0708	Power Problem	
2393	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
2394	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem	
									A1102	Application Program Problem	
2395	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	
									A090404	Output Above Specifications	

					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
2396	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2397	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2398	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem	06/12/2016	
									A26	Insufficient Device Problem Information	06/12/2016	
2399	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/12/2016	
2400	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	07/12/2016	
									A07	Electrical /Electronic Property Problem	05/12/2016	
									A0708	Power Problem	05/12/2016	
2401	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/05/2017	
									A0709	Device Sensing Problem	22/05/2017	
2402	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2403	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2404	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0721	Circuit Failure		
2405	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	11/10/2017	
									A0708	Power Problem	11/10/2017	
2406	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT1147	Defibrillators and associated devices	E1908	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT1150	Defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		

					CT233	Surgical	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2406	Implantable	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2407	Active implantable	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2985	Active	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT314	Electrically powered	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT981	Single use	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
2407	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2408	2018	All other reportable incidents			CT258	Implantable defibrillators	F1005	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/03/2018	
									A0708	Power Problem	22/03/2018	

2409	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	15/12/2016	
2410	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A17	Compatibility Problem	15/12/2016	
2411	2017	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	16/12/2016	
2412	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	16/12/2016	
2413	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
2414	2018	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0907	No Device Output		
2415	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0907	Electrical /Electronic Property Problem	07/11/2016	
2416	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	07/11/2016	
2417	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		

								L-exposure	A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
2418	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/01/2017	
									A0708	Power Problem	06/01/2017	
2419	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	01/08/2018	
									A0708	Power Problem	01/08/2018	
2420	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/01/2017	
									A0708	Power Problem	06/01/2017	
2421	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	16/08/2018	
									A0708	Power Problem	16/08/2018	
2422	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	05/01/2017	
									A0708	Power Problem	05/01/2017	
2423	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	21/11/2016	
									A0708	Power Problem	21/11/2016	
2424	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2425	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/12/2016	
									A0708	Power Problem	07/12/2016	
2426	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem	20/01/2017	
									A26	Insufficient Device Problem Information	20/01/2017	
2427	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	18/01/2017	
									A0708	Power Problem	18/01/2017	

2428	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	10/01/2017	
2429	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem	10/01/2017	
2430	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	10/01/2017	
2431	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Power Problem	10/01/2017	
2432	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
2433	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
2434	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A16	Protective Measures Problem		
2435	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1602	Fail-Safe Problem		
2436	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
2437	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2438	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
2439	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2440	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
2441	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem		
2442	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07	Power Problem	04/01/2017	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	04/01/2017	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A07	Power Problem	23/03/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	23/03/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A07	Power Problem	23/03/2018	
					CT1233	Surgical	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	23/03/2018	
					CT2406	Implantable	F1905	Device Revision or Replacement	A07	Power Problem	23/03/2018	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	23/03/2018	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	23/03/2018	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/03/2018	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A0708	Power Problem	23/03/2018	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/03/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0708	Power Problem	23/03/2018	
					CT2966	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/03/2018	
					CT2985	Active	F1905	Device Revision or Replacement	A0708	Power Problem	23/03/2018	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/03/2018	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0708	Power Problem	23/03/2018	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/03/2018	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0708	Power Problem	23/03/2018	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/03/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0708	Power Problem	23/03/2018	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/03/2018	
					CT981	Single use	F1905	Device Revision or Replacement	A0708	Power Problem	23/03/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/03/2018	
2443	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	23/03/2018	
2444	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
2445	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem		
2446	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0907	No Device Output		
2447	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem		
2448	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
2449	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		

2450	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2451	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem	05/01/2017	
									A0708	Power Problem	05/01/2017	
									A12	Connection Problem	05/01/2017	
									A1205	Loose or Intermittent Connection	05/01/2017	
2452	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A0907	No Device Output		
2453	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2454	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2455	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2456	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		

						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Device Sensing Problem Electrical /Electronic Property Problem		
						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Device Sensing Problem Electrical /Electronic Property Problem		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2457	2017	All other reportable incidents				CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0708	Electrical /Electronic Property Problem Power Problem	04/01/2017	
2458	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24 A26	No Apparent Device Problem Insufficient Device Problem Information	18/01/2017	
2459	2017	Death	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information	19/01/2017	
2460	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	21/08/2018	
								F1905	Device Revision or Replacement	A09 A090404	Output Problem Output Above Specifications	21/08/2018	

					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	21/08/2018		
							F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/08/2018		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	21/08/2018		
							F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/08/2018		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	21/08/2018		
							F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/08/2018		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	21/08/2018		
							F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/08/2018		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	21/08/2018		
							F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/08/2018		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	21/08/2018		
							F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/08/2018		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	21/08/2018		
							F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/08/2018		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem	21/08/2018		
							F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/08/2018		
2461	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	21/08/2018		
									A0709	Device Sensing Problem			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
2462	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
									A0708	Power Problem			
2463	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem			
									A090404	Output Above Specifications			
									A12	Connection Problem			
									A1205	Loose or Intermittent Connection			
2464	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
									A0708	Power Problem			
2465	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			

2466	2017	TBD			CT258	implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2467	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
									A07	Electrical /Electronic Property Problem		
2468	2017	All other reportable incidents			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A090502	Radiation Overexposure		
2469	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT1150	Defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT233	Surgical	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2406	Implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2407	Active implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT258	implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2985	Active	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT314	Electrically powered	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT981	Single use	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
2470	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2471	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	10/04/2018	
2472	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	10/04/2018	
2473	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/09/2018	
2474	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	20/09/2018	
2475	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	19/01/2017	
2476	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	19/01/2017	
2477	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/01/2017	
2478	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem	20/01/2017	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A09	Output Problem		

					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
2479	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404 A1104	Output Above Specifications Computer Operating System Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
2480	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
2481	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2482	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2483	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	22/06/2017	
2484	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem	22/08/2017	
2485	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2486	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	19/01/2017	
2487	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	19/01/2017	
2488	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem	02/07/2018	
2489	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0708	Electrical /Electronic Property Problem Power Problem	29/03/2018	
2490	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2491	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2492	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		

2493	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2494	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2495	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2496	2018	Unanticipated serious deterioration in state of health			CT258	Implantable defibrillators			A07 A26	Device Sensing Problem Insufficient Device Problem Information		
2497	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2498	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2499	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2500	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24 A26	No Apparent Device Problem Insufficient Device Problem Information	23/01/2017 23/01/2017	
2501	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	13/01/2017	
2502	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	24/01/2017 24/01/2017	
2503	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	24/01/2017 24/01/2017	
2504	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
2505	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2506	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2507	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2508	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	28/08/2018 28/08/2018	
2509	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2510	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2511	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	19/03/2018 19/03/2018	
2512	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2513	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		

2514	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
2515	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A01	Patient Device Interaction Problem	05/01/2017	
									A07	Electrical /Electronic Property Problem	05/01/2017	
									A0708	Power Problem	05/01/2017	
							F1905	Device Revision or Replacement	A17	Compatibility Problem	05/01/2017	
									A01	Patient Device Interaction Problem	05/01/2017	
									A07	Electrical /Electronic Property Problem	05/01/2017	
2516	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	05/01/2017	
									A17	Compatibility Problem	05/01/2017	
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2517	2018	All other reportable incidents			CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
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									2517	2018	All other reportable incidents	
2518	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A11	Power Problem	24/03/2018	
									A1102	Computer Software Problem		
2519	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Application Program Problem		
									A0709	Electrical /Electronic Property Problem		
									A26	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A26	Insufficient Device Problem Information		
									A0709	Electrical /Electronic Property Problem		
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A26	Insufficient Device Problem Information											
A0709	Electrical /Electronic Property Problem											
A07	Device Sensing Problem											

					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem		
2520	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	26/10/2017	

					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	26/10/2017	
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	26/10/2017	
									A07	Electrical /Electronic Property Problem	26/10/2017	
									A0709	Device Sensing Problem	26/10/2017	
2521	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		

2537	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	05/01/2017	
2538	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	05/01/2017	
									A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2539	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT2886	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
2540	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/01/2017	
									A0708	Power Problem	20/01/2017	
2541	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A09	Device Sensing Problem		
									A090404	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A09	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		

						CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
2542	2017	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090404 A24	Output Above Specifications No Apparent Device Problem	16/01/2017	
2543	2017	TBD				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26 A07 A0709	Insufficient Device Problem Information Electrical /Electronic Property Problem Device Sensing Problem	16/01/2017	
2544	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708 A0709	Electrical /Electronic Property Problem Power Problem Device Sensing Problem	13/04/2018	
2545	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	13/04/2018	
2546	2017	TBD				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2547	2018	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	09/08/2018	
2548	2018	All other reportable incidents				CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications	09/08/2018	
2549	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
						CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		

					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
2550	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	19/01/2017	
2551	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2109	Implant Pain	A01	Patient Device Interaction Problem	19/01/2017	
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT1147	Defibrillators and associated devices	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT1150	Defibrillators	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT145	Cardiovascular devices	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT233	Surgical	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2406	Implantable	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2407	Active implantable	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT258	Implantable defibrillators	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT263	Cardiographs and associated devices	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2727	Active implant devices/ancillaries	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators	E2109	Implant Pain	A01	Patient Device Interaction Problem		

							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT2985	Active	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3001	Implantable metal	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3006	Implantable inorganic material	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3007	Implantable ceramic	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT314	Electrically powered	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT449	Generators and associated devices	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT981	Single use	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT983	Surgical invasive	E2109	Implant Pain	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
2552	2017	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
2553	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/01/2017	
2554	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	25/01/2017	
2555	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2556	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	09/04/2018	
2557	2017	TBD			CT258	Implantable defibrillators	E2401	Insufficient Information	A0708	Power Problem	09/04/2018	
							F21	Unexpected Deterioration	A0709	Device Sensing Problem		
2558	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2559	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
2560	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090404	Output Above Specifications	21/07/2018	

								A0708	Power Problem	21/07/2018	
2561	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A16	Protective Measures Problem	
2562	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1602	Fail-Safe Problem	
2563	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A13	Communication or Transmission Problem	
2564	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
2565	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1104	Computer Operating System Problem	
2566	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	
2567	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	29/03/2018
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	29/03/2018
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem	01/10/2015
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem	01/10/2015
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0104	Migration or Expulsion of Device	
2568	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	24/01/2017
2569	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	24/01/2017
2570	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	26/03/2018
2571	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem	26/03/2018
2572	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
2573	2017	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A11	Computer Software Problem	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1102	Application Program Problem	
							F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	
2574	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	
2575	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	30/01/2017
2576	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	30/01/2017
2577	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A12	Connection Problem	05/01/2017
2578	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1204	Failure to Disconnect	05/01/2017
2579	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	31/01/2017
2580	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A0708	Power Problem	01/04/2018
2581	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	01/04/2018
2582	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	05/09/2018
									A0708	Power Problem	05/09/2018
									A16	Protective Measures Problem	
									A1601	Device Alarm System	

2583	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A16 A1602	Protective Measures Problem Fail-Safe Problem		
2584	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	10/09/2018 10/09/2018	
2585	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2586	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2587	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2588	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2589	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2590	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A26	Telemetry Discrepancy Insufficient Device Problem Information		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
2591	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2592	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/01/2017	
									A0708	Power Problem	27/01/2017	
2593	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	31/01/2017	
									A0708	Power Problem	31/01/2017	
2594	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/01/2017	
									A0708	Power Problem	27/01/2017	
2595	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	10/01/2017	
									A0708	Power Problem	10/01/2017	
2596	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	31/01/2017	
									A0708	Power Problem	31/01/2017	
2597	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	12/09/2018	
									A0708	Power Problem	12/09/2018	
2598	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
2599	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2600	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2601	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2602	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/01/2017	
									A0708	Power Problem	06/01/2017	

2603	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	02/02/2017	
2604	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	02/02/2017	
2605	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	21/01/2017	
2606	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	21/01/2017	
2607	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem	21/01/2017	
2608	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	21/01/2017	
2609	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/12/2016	
2610	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	23/12/2016	
2611	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	30/01/2017	
2612	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	30/01/2017	
2613	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A16	Protective Measures Problem	19/05/2017	
2614	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System	19/05/2017	
2615	2017	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A07	Electrical /Electronic Property Problem	12/04/2012	
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A0708	Power Problem		
					CT1150	Defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT233	Surgical	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT2406	Implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT2407	Active implantable	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT2985	Active	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT314	Electrically powered	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem		
					CT981	Single use	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A17	Compatibility Problem		
2616	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A01	Patient Device Interaction Problem		
2617	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A16	Protective Measures Problem		
2618	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1602	Fail-Safe Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		

					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2619	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2620	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem	06/02/2017	
2621	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	06/02/2017	
2622	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	02/02/2017	
									A0708	Power Problem	02/02/2017	
									A07	Electrical /Electronic Property Problem	03/02/2017	
									A0708	Power Problem	03/02/2017	

						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
2629	2018	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2630	2017	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/02/2017	
										A0708	Power Problem	07/02/2017	
										A0709	Device Sensing Problem	07/02/2017	
2631	2017	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/02/2017	
										A0708	Power Problem	06/02/2017	
2632	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	31/01/2017	
										A0708	Power Problem	31/01/2017	
2633	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	18/04/2018	
										A0708	Power Problem	18/04/2018	
2634	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A24	No Apparent Device Problem	31/01/2017	
										A26	Insufficient Device Problem Information	31/01/2017	
2635	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem	31/01/2017	
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/01/2017	
										A24	No Apparent Device Problem	31/01/2017	
2636	2017	TBD				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2637	2017	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2638	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
2639	2017	All other reportable incidents				CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2640	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A16	Protective Measures Problem		
										A1601	Device Alarm System		
2641	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	24/01/2017	
										A0708	Power Problem	24/01/2017	
2642	2017	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2643	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/08/2018	
										A0708	Power Problem	22/08/2018	
2644	2017	Death	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F21	Unexpected Deterioration	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2645	2017	TBD				CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2646	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2647	2017	All other reportable incidents				CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2648	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2649	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
										A26	Insufficient Device Problem Information		
2650	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A04	Material Integrity Problem	06/04/2018	
										A0404	Crack	06/04/2018	
2651	2018	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	10/04/2018	
										A0708	Power Problem	10/04/2018	
2652	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	04/07/2018	
										A0709	Device Sensing Problem	04/07/2018	
2653	2017	TBD				CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A26	Insufficient Device Problem Information		
2654	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0708	Power Problem		
2655	2017	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	06/11/2017	
										A0708	Power Problem	06/11/2017	
2656	2017	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/11/2017	
										A0708	Power Problem	13/11/2017	
2657	2018	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
2658	2017	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
										A090404	Output Above Specifications		
										A090502	Radiation Overexposure		
2659	2017	TBD	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		

2663	2017	TBD			CT258	Implantable defibrillators	F1905	Exposure	Device Revision or Replacement	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
2664	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
2665	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
										A11	Computer Software Problem		
2666	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement		A1102	Application Program Problem		
										A07	Electrical /Electronic Property Problem	20/06/2017	
2667	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0708	Power Problem	20/06/2017	
										A07	Electrical /Electronic Property Problem		
2668	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
2669	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A0709	Device Sensing Problem		
										A070909	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		
										A26	Insufficient Device Problem Information		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions		A11	Computer Software Problem		
										A1102	Application Program Problem		
										A1304	Telemetry Discrepancy		

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A26 A11 A1102 A1304	Insufficient Device Problem Information Computer Software Problem Application Program Problem Telemetry Discrepancy		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A26 A11 A1102 A1304	Insufficient Device Problem Information Computer Software Problem Application Program Problem Telemetry Discrepancy		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26 A11 A1102 A1304	Insufficient Device Problem Information Computer Software Problem Application Program Problem Telemetry Discrepancy		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A26 A11 A1102 A1304	Insufficient Device Problem Information Computer Software Problem Application Program Problem Telemetry Discrepancy		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A26 A11 A1102 A1304	Insufficient Device Problem Information Computer Software Problem Application Program Problem Telemetry Discrepancy		
2670	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A26 A01 A17	Insufficient Device Problem Information Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT1150	Defibrillators	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT233	Surgical	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2406	Implantable	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2407	Active implantable	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2985	Active	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
							F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem		

					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT3007	implantable ceramic	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT314	Electrically powered	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT981	Single use	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
2671	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2672	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
2673	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2674	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2678	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2679	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
									A07	Patient Device Interaction Problem	27/11/2017	
									A17	Compatibility Problem	27/11/2017	
									A07	Patient Device Interaction Problem	27/11/2017	
									A17	Compatibility Problem	27/11/2017	
2680	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	05/09/2018	
									A0708	Power Problem	05/09/2018	
2681	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2682	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	07/12/2017	
									A0708	Power Problem	07/12/2017	
2683	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2684	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2685	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
2686	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		

					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
2687	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2688	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2689	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT1147	Defibrillators and associated devices	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT1150	Defibrillators	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT141	Electrodes/Leads and associated devices	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT145	Cardiovascular devices	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT233	Surgical	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT2406	Implantable	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT2407	Active implantable	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT258	Implantable defibrillators	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT263	Cardiographs and associated devices	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT2726	Physiological monitoring/measuring devices	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT2727	Active implant devices/ancillaries	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT2866	Implantable cardiac electrical stimulators	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT2985	Active	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT3001	Implantable metal	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT3002	Implantable synthetic polymer	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		
					CT3006	Implantable inorganic material	F1001	Absence of Treatment	A12	Connection Problem		
									A1206	Misconnection		

					CT3007	Implantable ceramic	F1001	Absence of Treatment	A12	Connection Problem			
					CT314	Electrically powered	F1001	Absence of Treatment	A1206	Misconnection			
					CT321	Long-term surgical invasive	F1001	Absence of Treatment	A12	Connection Problem			
					CT449	Generators and associated devices	F1001	Absence of Treatment	A1206	Misconnection			
					CT981	Single use	F1001	Absence of Treatment	A12	Connection Problem			
					CT983	Surgical invasive	F1001	Absence of Treatment	A1206	Misconnection			
2690	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT1150	Defibrillators	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT145	Cardiovascular devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT233	Surgical	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2406	Implantable	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2407	Active implantable	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT258	Implantable defibrillators	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2985	Active	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT3001	Implantable metal	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT3007	Implantable ceramic	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT314	Electrically powered	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT449	Generators and associated devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT981	Single use	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT983	Surgical invasive	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
2691	2018	Death			CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information			
2692	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
2693	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	16/02/2017		
									A0708	Power Problem	16/02/2017		
2694	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0708	Power Problem			
2695	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT1150	Defibrillators	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT145	Cardiovascular devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT233	Surgical	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2406	Implantable	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2407	Active implantable	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT258	Implantable defibrillators	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A09	Output Problem			
									A090404	Output Above Specifications			

					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A09	Output Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT2985	Active	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT3001	Implantable metal	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT3007	Implantable ceramic	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT314	Electrically powered	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT449	Generators and associated devices	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT981	Single use	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
					CT983	Surgical invasive	E2104	Electric Shock	A090404	Output Above Specifications			
									A09	Output Problem			
2696	2017	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information			
2697	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	26/06/2017		
									A0708	Power Problem			
2698	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	26/06/2017		
2699	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
2700	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0708	Power Problem			
2701	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
2702	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
2703	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem			
									A090404	Output Above Specifications			
2704	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	15/12/2017		

2705	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	15/12/2017	
									A07	Electrical /Electronic Property Problem		
2706	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
									A0203	Defective Device		
									A09	Output Problem		
2707	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0907	No Device Output	23/04/2018	
									A07	Electrical /Electronic Property Problem		
2708	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	23/04/2018	
									A13	Communication or Transmission Problem	27/01/2017	
2709	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A28	Insufficient Device Problem Information	27/01/2017	
									A07	Electrical /Electronic Property Problem	12/08/2016	
2710	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	12/08/2016	
									A07	Electrical /Electronic Property Problem		
2711	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A0709	Device Sensing Problem		
									A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
									F1905	Device Revision or Replacement		
									A01	Patient Device Interaction Problem		
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT1150	Defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
									F1905	Device Revision or Replacement		
									A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT233	Surgical	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT2406	Implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT2407	Active implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A17	Compatibility Problem		
									F1905	Device Revision or Replacement		
									A01	Patient Device Interaction Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A17	Compatibility Problem		
									F1905	Device Revision or Replacement		
									A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT2985	Active	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A17	Compatibility Problem		
									F1905	Device Revision or Replacement		
									A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									F1905	Device Revision or Replacement		
									A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A17	Compatibility Problem		
									F1905	Device Revision or Replacement		
									A01	Patient Device Interaction Problem		

					CT314	Electrically powered	E1906	Unspecified Infection	A17	Compatibility Problem		
							F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem		
							F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT981	Single use	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A17	Compatibility Problem		
							F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
2712	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2713	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	07/12/2017	
									A0708	Power Problem	07/12/2017	
2714	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
2715	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2716	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2717	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2718	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
2719	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2720	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem	16/11/2017	
2721	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	08/12/2017	
2722	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	08/12/2017	
2723	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Electrical /Electronic Property Problem		
2724	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Device Sensing Problem		
2725	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Electrical /Electronic Property Problem		
2726	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
2727	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A11	Computer Software Problem		
2728	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1102	Application Program Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A12	Connection Problem	26/10/2017	
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1206	Misconnection	26/10/2017	
					CT1145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		

					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2729	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2730	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	18/09/2018	
2731	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	18/09/2018	
2732	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2733	2018	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A0708	Power Problem		
2734	2017	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A01	Patient Device Interaction Problem		
2735	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A17	Compatibility Problem		
2736	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem	29/06/2017	
2737	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output	01/01/2018	
2738	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	24/04/2018	
2739	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	24/04/2018	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2740	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2741	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2742	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	17/08/2018	
									A0708	Power Problem	17/08/2018	

2743	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
							F1905	Device Revision or Replacement	A0708	Power Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2748	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	17/05/2016	
2749	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	17/05/2016	
2750	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	20/04/2018	
2751	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/04/2018	
2752	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
2753	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	30/06/2017	
2754	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	30/06/2017	
2755	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/12/2017	
2756	2017	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	23/02/2017	
2757	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/02/2017	
2758	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	03/05/2018	
2759	2017	TBD	35862	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	03/05/2018	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		

2760	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A26	Insufficient Device Problem Information		
2761	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
2762	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2766	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	08/12/2017	
2767	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/12/2017	
2768	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2769	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2770	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
2771	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
2772	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
2773	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		

					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2774	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
2775	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

									A0709	Device Sensing Problem		
2776	2018	Death			CT258	implantable defibrillators			A16	Protective Measures Problem		
									A1602	Fail-Safe Problem		
2777	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2778	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2779	2017	All other reportable incidents			CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2780	2018	All other reportable incidents			CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	19/09/2018	
									A0708	Power Problem	19/09/2018	
2781	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2782	2018	All other reportable incidents			CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	19/09/2018	
									A0708	Power Problem	19/09/2018	
2783	2017	TBD			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2784	2017	All other reportable incidents			CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2785	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2786	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2787	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2788	2018	All other reportable incidents			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2789	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	10/07/2017	
									A0708	Power Problem	10/07/2017	
2790	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	04/07/2017	
									A0708	Power Problem	04/07/2017	
2791	2017	TBD			CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2792	2017	TBD			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2793	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
									A0709	Device Sensing Problem		
2794	2017	TBD			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2795	2017	All other reportable incidents			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2796	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT233	Surgical	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT3006	implantable inorganic material	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		

2797	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2798	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
2799	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
2800	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
2801	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2802	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2803	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2804	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2805	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
2806	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	03/02/2017	
2807	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	03/02/2017	
2808	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
2809	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2810	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
2811	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2812	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

2817	2017	TBD	35852	Single-chamber implantable defibrillator	CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
2818	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2819	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2820	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		

						CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
										A09	Output Problem		
2821	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications			
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
										A0709	Device Sensing Problem		

					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2822	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2823	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/04/2018	
									A0708	Power Problem	25/04/2018	
2824	2017	Death			CT258	Implantable defibrillators	F21	Unexpected Deterioration	A09	Output Problem	18/12/2017	
									A0907	No Device Output	18/12/2017	
2825	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/05/2018	
									A0708	Power Problem	14/05/2018	
2826	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/12/2017	
									A0708	Power Problem	07/12/2017	
2827	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	19/12/2017	
									A0708	Power Problem	19/12/2017	
2828	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0722	Impedance Problem		
									A072201	High Impedance		
2829	2017	All other reportable incidents			CT258	Implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2830	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0708	Power Problem	15/10/2018		
									A07	Electrical /Electronic Property Problem	15/10/2018		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0708	Power Problem	15/10/2018		
									A07	Electrical /Electronic Property Problem	15/10/2018		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0708	Power Problem	15/10/2018		
									A07	Electrical /Electronic Property Problem	15/10/2018		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A0708	Power Problem	15/10/2018		
									A07	Electrical /Electronic Property Problem	15/10/2018		
					CT981	Single use	F1905	Device Revision or Replacement	A0708	Power Problem	15/10/2018		
									A07	Electrical /Electronic Property Problem	15/10/2018		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0708	Power Problem	15/10/2018		
									A07	Electrical /Electronic Property Problem	15/10/2018		
2833	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	15/10/2018		
									A07	Electrical /Electronic Property Problem	15/10/2018		
2834	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
									A0708	Electrical /Electronic Property Problem	28/09/2018		
									A0708	Power Problem	28/09/2018		
2835	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	02/10/2018		
									A0708	Power Problem	02/10/2018		
2836	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
									A0708	Power Problem			
2837	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	26/02/2018		
									A0708	Power Problem	26/02/2018		
2838	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	21/12/2017		
									A0708	Power Problem	21/12/2017		
2839	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
2840	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	06/12/2017		
									A0708	Power Problem	06/12/2017		
									A07	Electrical /Electronic Property Problem	06/12/2017		
									A0708	Power Problem	06/12/2017		
2841	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	06/12/2017		
									A0709	Device Sensing Problem			
									A070909	Oversensing			
									A0722	Impedance Problem			
									A072201	High Impedance			
2842	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/12/2017		
									A0708	Power Problem	08/12/2017		
2843	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/12/2017		
									A0708	Power Problem	07/12/2017		
2844	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/08/2017		
									A0708	Power Problem	07/08/2017		
2845	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
2846	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem			
									A26	Insufficient Device Problem Information			
2847	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
									A0709	Device Sensing Problem			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			

					CT3006	Implantable inorganic material	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
2851	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2852	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
2853	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
2854	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
2855	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
2856	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2857	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2858	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	10/02/2017	
2859	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	10/02/2017	
2860	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	08/12/2017	
2861	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Electrical /Electronic Property Problem	06/12/2017	
2862	2018	Unanticipated serious deterioration in state of health			CT258	Implantable defibrillators			A28	Insufficient Device Problem Information		
2863	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	06/12/2017	
2864	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		

2865	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
2866	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A090502	Electrical /Electronic Property Problem Device Sensing Problem Radiation Overexposure		
2867	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	08/08/2017 08/08/2017	
2868	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT1150	Defibrillators	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT233	Surgical	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2406	Implantable	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2407	Active implantable	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT2985	Active	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3001	Implantable metal	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT314	Electrically powered	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT981	Single use	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
					CT983	Surgical invasive	E1906	Unspecified Infection	A01 A17	Patient Device Interaction Problem Compatibility Problem		
2869	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
2870	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	12/10/2017 12/10/2017	
2871	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	07/12/2017 07/12/2017	
2872	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A0907	Output Problem No Device Output		
2873	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2874	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2875	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2876	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2877	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2878	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem	23/05/2018 23/05/2018	
2879	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
2880	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2881	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070910	Electrical /Electronic Property Problem Device Sensing Problem Undersensing		
2882	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2883	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	23/01/2018 23/01/2018	
2884	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

2885	2018	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A0708	Power Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
2886	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2888	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
2889	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
					CT1147	Defibrillators and associated devices	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
					CT1150	Defibrillators	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
					CT141	Electrodes/Leads and associated devices	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
					CT145	Cardiovascular devices	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
					CT233	Surgical	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
					CT2406	Implantable	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
					CT2407	Active implantable	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
					CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
					CT263	Cardiographs and associated devices	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
					CT2727	Active implant devices/ancillaries	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
					CT2866	Implantable cardiac electrical stimulators	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
					CT2985	Active	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
					CT3001	Implantable metal	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
									A01	Patient Device Interaction Problem		

					CT3002	Implantable synthetic polymer	E0402	Hypersensitivity/Allergic Reaction	A17	Compatibility Problem		
					CT3006	Implantable inorganic material	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT3007	Implantable ceramic	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT314	Electrically powered	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT321	Long-term surgical invasive	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT449	Generators and associated devices	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT981	Single use	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
					CT983	Surgical invasive	E0402	Hypersensitivity/Allergic Reaction	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
2890	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
2891	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	19/12/2017	
									A0708	Power Problem	19/12/2017	
2892	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A07	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT3006	Implantable inorganic material	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	implantable ceramic	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2893	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A16	Protective Measures Problem		
									A1602	Fail-Safe Problem		
2894	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2895	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2896	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
2897	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT233	Surgical	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT2406	Implantable	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT258	implantable defibrillators	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT2750	implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT2866	implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT2985	Active	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT3002	implantable synthetic polymer	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		

					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT981	Single use	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
									A0104	Migration or Expulsion of Device		
									A17	Compatibility Problem		
2898	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/12/2017	
									A0708	Power Problem	13/12/2017	
2899	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	12/11/2017	
									A0709	Device Sensing Problem	12/11/2017	
2900	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2901	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2902	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	23/05/2018	
									A0708	Power Problem	23/05/2018	
2903	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	11/10/2018	
									A0708	Power Problem	11/10/2018	
2904	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/05/2018	
									A0708	Power Problem	23/05/2018	
2905	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2906	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2907	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
2908	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	28/12/2017	
									A0708	Power Problem	28/12/2017	
2909	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2910	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/03/2017	
									A0708	Power Problem	06/03/2017	
2911	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2912	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2913	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		

					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
2914	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2915	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2916	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2917	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2918	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
2919	2017	All other reportable incidents			CT258	Implantable defibrillators	E2401	Insufficient Information	A1102	Application Program Problem		
2920	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A0704	Migration or Expulsion of Device		
									A0709	Electrical /Electronic Property Problem		
2921	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	25/05/2018	
									A07	Electrical /Electronic Property Problem		
									A0708	Power Problem	25/05/2018	
2922	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	09/06/2018	
									A0708	Power Problem	09/06/2018	
2923	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	04/01/2018	
									A0708	Power Problem	04/01/2018	
2924	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	10/02/2017	
									A0708	Power Problem	10/02/2017	
2925	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
2926	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2927	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2928	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2929	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
2930	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

2931	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	23/05/2018	
2932	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	23/05/2018	
2933	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2934	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2935	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices			A0709	Device Sensing Problem		
					CT1150	Defibrillators			A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators			A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices			A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices			A0709	Device Sensing Problem		
					CT233	Surgical			A07	Electrical /Electronic Property Problem		
					CT2406	Implantable			A0709	Device Sensing Problem		
					CT2407	Active implantable			A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators			A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices			A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices			A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries			A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices			A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators			A07	Electrical /Electronic Property Problem		
					CT2985	Active			A0709	Device Sensing Problem		
					CT3001	Implantable metal			A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer			A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material			A07	Electrical /Electronic Property Problem		

					CT3007	Implantable ceramic			A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered			A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive			A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices			A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT981	Single use			A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive			A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
2936	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	15/01/2018	
									A07	Electrical /Electronic Property Problem		
2937	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	15/01/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT233	Surgical	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT2406	Implantable	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT2985	Active	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT981	Single use	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A17	Compatibility Problem	01/10/2018	
									A01	Patient Device Interaction Problem	01/10/2018	
2938	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
2939	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	14/05/2018	
2940	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	14/05/2018	
2941	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		

					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A07 A0713 A071302	Inappropriate/Inadequate Shock/Stimulation Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
2942	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A071302 A0708	Electrical /Electronic Property Problem Power Problem	13/06/2018	
2943	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A07 A0709 A070909	Oversensing Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
2944	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
2945	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A07	Device Sensing Problem Electrical /Electronic Property Problem	27/12/2017	
2946	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708 A07	Power Problem Electrical /Electronic Property Problem	27/12/2017 22/12/2017	
									A0708	Power Problem	22/12/2017	

2947	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2948	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2949	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2950	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0708	Power Problem		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT233	Surgical	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2104	Electric Shock	A07	Electrical /Electronic Property Problem		
2951	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2952	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
2953	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	07/03/2017	
2954	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	20/12/2017	
2955	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
2956	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2957	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
2958	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	24/10/2018	
2959	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	24/05/2018	
2960	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	24/05/2018	
2961	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
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									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		

					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT233	Surgical	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT2406	Implantable	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT2985	Active	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT981	Single use	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A090404	Output Above Specifications		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
2962	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2963	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
2964	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	31/05/2018	
									A0708	Power Problem	31/05/2018	
2965	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2966	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2967	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2968	2018	All other reportable incidents			CT258	implantable defibrillators	F14	Prolonged Episode of Care	A0703	Arcing		
2969	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
2970	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
2971	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2972	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
2973	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
2974	2017	TBD			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
2975	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
2976	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2977	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		

					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
2978	2018	Death			CT258	Implantable defibrillators	F21	Unexpected Deterioration	A07	Electrical /Electronic Property Problem		
2979	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
2980	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	03/01/2018	
2981	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	03/01/2018	
2982	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	04/01/2018	
2983	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem	04/01/2018	
2984	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	26/07/2017	
2985	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem	26/07/2017	
2986	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Electrical /Electronic Property Problem	15/06/2018	
2987	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	15/06/2018	
2988	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2989	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
2990	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/02/2017	
2991	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	20/02/2017	
2992	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
2993	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	25/10/2018	
2994	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
2995	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
2996	2018	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/10/2018	
2997	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	23/10/2018	
2998	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	21/05/2018	
2999	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	21/05/2018	
3000	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3001	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		

CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
3006	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem	09/01/2018	
3007	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	09/01/2018	
									A11	Computer Software Problem		
									A1102	Application Program Problem		
									A1304	Telemetry Discrepancy		
3008	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
3009	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3010	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem		
									A090404	Output Above Specifications		
3011	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
3012	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3013	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3014	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3015	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
3016	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
3017	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	22/10/2018	
3018	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A11	Computer Software Problem		
							F05	Delay to Treatment/ Therapy	A1102	Application Program Problem		
									A11	Computer Software Problem		
									A1102	Application Program Problem		
3019	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
3020	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
3021	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	09/01/2018	
									A0708	Power Problem		
									A0709	Electrical /Electronic Property Problem	09/01/2018	
									A0709	Device Sensing Problem		
									A070909	Oversensing		
3022	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A1104	Computer Operating System Problem		
3023	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		

						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
3024	2018	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem	29/10/2018	
3025	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		29/10/2018	
3026	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Electrical /Electronic Property Problem	03/03/2017		
										A07	Power Problem	03/03/2017	
3027	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	07/03/2017		
										A07	Power Problem	07/03/2017	
3028	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem			
										A07	Power Problem	10/01/2018	
3029	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	10/01/2018		
										A07	Electrical /Electronic Property Problem		
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
3030	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem			
3031	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem			
3032	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090404	Output Above Specifications			
3033	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem	21/01/2018		
										A07	Power Problem	21/01/2018	
3034	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Electrical /Electronic Property Problem	01/02/2018		
										A07	Power Problem	01/02/2018	
3035	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	25/10/2018		
3036	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem	25/10/2018		
										A07	Electrical /Electronic Property Problem		
3037	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	26/10/2018		
										A07	Power Problem	26/10/2018	
3038	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem			
3039	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem			
										A07	Electrical /Electronic Property Problem		
3040	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem			
										A07	Electrical /Electronic Property Problem		
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A07	Electrical /Electronic Property Problem		
										A0709	Device Sensing Problem		

					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3041	2017	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
3042	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
3043	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A24	No Apparent Device Problem		
3044	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
3045	2018	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
3046	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3047	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		

					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
3048	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
3049	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
3050	2018	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F21	Unexpected Deterioration	A0709	Device Sensing Problem		
									A13	Communication or Transmission Problem	17/01/2018	
					CT1147	Defibrillators and associated devices	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information	17/01/2018	
					CT1150	Defibrillators	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT141	Electrodes/Leads and associated devices	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT145	Cardiovascular devices	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT233	Surgical	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT2406	Implantable	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT2407	Active implantable	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT258	Implantable defibrillators	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT263	Cardiographs and associated devices	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT2726	Physiological monitoring/measuring devices	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT2727	Active implant devices/ancillaries	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT2866	Implantable cardiac electrical stimulators	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT2985	Active	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT3001	Implantable metal	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT3002	Implantable synthetic polymer	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT3006	Implantable inorganic material	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT3007	Implantable ceramic	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT314	Electrically powered	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT321	Long-term surgical invasive	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT449	Generators and associated devices	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT981	Single use	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
					CT983	Surgical invasive	F21	Unexpected Deterioration	A13	Communication or Transmission Problem	17/01/2018	
									A26	Insufficient Device Problem Information	17/01/2018	
3051	2018	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3052	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		

						CT2726	Physiological monitoring/measuring devices	F10	Exposure	A0709	Device Sensing Problem		
						CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
						CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3053	2017	TBD				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3054	2018	All other reportable incidents				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
3055	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A12	Connection Problem		
						CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT258	implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT3002	implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT3007	implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1104	Computer Operating System Problem		
3056	2018	All other reportable incidents				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem		
3057	2017	TBD				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
3058	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3059	2018	All other reportable incidents				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3060	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Power Problem		
3061	2018	All other reportable incidents				CT258	implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/10/2018	
										A0708	Power Problem	22/10/2018	

3062	2018	All other reportable incidents			CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A16	Protective Measures Problem	04/06/2018	
3063	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A13	Communication or Transmission Problem	04/06/2018	
							F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	04/06/2018	
									A13	Communication or Transmission Problem	04/06/2018	
3064	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	04/06/2018	
3065	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
									A07	Electrical /Electronic Property Problem	19/10/2018	
3066	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	19/10/2018	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
A0709	Device Sensing Problem											
3067	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
3068	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3069	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
3070	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem	12/11/2017	
									A0709	Device Sensing Problem	12/11/2017	
3071	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3072	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3073	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A09	Output Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A09	Output Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A09	Output Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A09	Output Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A09	Output Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A09	Output Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
A09	Output Problem											
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings							
				A09	Output Problem							

					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
3074	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
3075	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	21/03/2017	
3076	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	21/03/2017	
3077	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3078	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3079	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
3080	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

3081	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708 A09 A090404	Power Problem Output Problem Output Above Specifications		
3082	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A01 A17	Patient Device Interaction Problem Compatibility Problem	10/01/2018 10/01/2018	
3083	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	08/01/2018 08/01/2018	
3084	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	09/01/2018	
3085	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708 A11 A1102	Power Problem Computer Software Problem Application Program Problem	09/01/2018	
3086	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404 A1104	Output Problem Output Above Specifications Computer Operating System Problem		
3087	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1150	Defibrillators	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT145	Cardiovascular devices	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT233	Surgical	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2406	Implantable	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2407	Active implantable	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT258	Implantable defibrillators	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2985	Active	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3001	Implantable metal	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3007	Implantable ceramic	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT314	Electrically powered	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT449	Generators and associated devices	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT981	Single use	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT983	Surgical invasive	E2104	Electric Shock	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3088	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
3089	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem	02/11/2018 02/11/2018	
3090	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07 A0708	Power Problem Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT233	Surgical	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT2406	Implantable	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A26 A13	Insufficient Device Problem Information Communication or Transmission Problem	15/06/2018 15/06/2018	

					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	15/06/2018	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	15/06/2018	
					CT2985	Active	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	15/06/2018	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	15/06/2018	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	15/06/2018	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	15/06/2018	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	15/06/2018	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	15/06/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	15/06/2018	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	15/06/2018	
					CT981	Single use	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	15/06/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	15/06/2018	
3091	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	15/06/2018	
3092	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	14/06/2018	
3093	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	14/06/2018	
3094	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
3095	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3096	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3097	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3098	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	20/06/2018	
									A0708	Power Problem	20/06/2018	

3099	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
3100	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1102	Application Program Problem		
									A07	Electrical/Electronic Property Problem	03/04/2017	
									A0708	Power Problem	03/04/2017	
3101	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090503	Radiation Underexposure		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1104	Computer Operating System Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		

3114	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3115	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3116	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2886	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3117	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3118	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
3119	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
3120	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
3121	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/06/2018	
3122	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	22/06/2018	
3123	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	12/06/2018	
3124	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	12/06/2018	
3125	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	18/01/2018	
3126	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem	04/07/2018	
3126					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	04/07/2018	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A07	Electrical /Electronic Property Problem		
									A07	Electrical /Electronic Property Problem		
									A07	Electrical /Electronic Property Problem		

				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018

				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	09/11/2018
				A0708	Power Problem	08/11/2018	09/11/2018
				A0709	Device Sensing Problem	08/11/2018	09/11/2018
				A072202	Low Impedance	08/11/2018	09/11/2018
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	09/11/2018
				A0705	Battery Problem	08/11/2018	09/11/2018

				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A07008	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A07008	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A07009	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018

				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018
		F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem	08/11/2018	08/11/2018
				A0705	Battery Problem	08/11/2018	08/11/2018
				A070504	Premature Discharge of Battery	08/11/2018	08/11/2018
				A0708	Power Problem	08/11/2018	08/11/2018
				A0709	Device Sensing Problem	08/11/2018	08/11/2018
				A072202	Low Impedance	08/11/2018	08/11/2018

					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0705 A070504 A0708 A0709 A072202	Electrical /Electronic Property Problem Battery Problem Premature Discharge of Battery Power Problem Device Sensing Problem Low Impedance	08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018	08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018
							F1905	Device Revision or Replacement	A07 A0705 A070504 A0708 A0709 A072202	Electrical /Electronic Property Problem Battery Problem Premature Discharge of Battery Power Problem Device Sensing Problem Low Impedance	08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018	08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018
							F26	No Health Consequences or Impact	A07 A0705 A070504 A0708 A0709 A072202	Electrical /Electronic Property Problem Battery Problem Premature Discharge of Battery Power Problem Device Sensing Problem Low Impedance	08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018	08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018 08/11/2018
3129	2018	150	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3130	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2007	Fail	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
					CT1147	Defibrillators and associated devices	E2007	Fail	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
					CT1150	Defibrillators	E2007	Fail	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Electrical /Electronic Property Problem Device Sensing Problem Output Problem		

CT141	Electrodes/Leads and associated devices	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT145	Cardiovascular devices	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT233	Surgical	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT2406	Implantable	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT2407	Active implantable	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT258	Implantable defibrillators	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT263	Cardiographs and associated devices	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT2726	Physiological monitoring/measuring devices	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT2727	Active implant devices/ancillaries	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
CT2866	Implantable cardiac electrical stimulators	E2007	Fail	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A07	Electrical /Electronic Property Problem		
				A0709	Device Sensing Problem		
				A09	Output Problem		

3134	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A07	Electrical /Electronic Property Problem			
								A0709	Device Sensing Problem			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT1145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
3135	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
3136	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT1145	Cardiovascular devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT233	Surgical	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2406	Implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2407	Active implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT2985	Active	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
								A0709	Device Sensing Problem			

					CT314	Electrically powered	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
					CT981	Single use	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
3137	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3138	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3139	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A11	Computer Software Problem		
									A1102	Application Program Problem		
									A16	Protective Measures Problem		
									A1602	Fail-Safe Problem		
3140	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
3141	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
3142	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
									A0708	Power Problem		
3143	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A0708	Power Problem		
3144	2018	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A0709	Device Sensing Problem	18/08/2018	
									A07	Electrical /Electronic Property Problem	18/08/2018	
3145	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	22/08/2018	
									A0708	Power Problem	22/08/2018	
3146	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	21/08/2018	
									A0708	Power Problem	21/08/2018	
3147	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
									A0709	Device Sensing Problem	14/11/2018	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	14/11/2018	
							F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	14/11/2018	
									A07	Electrical /Electronic Property Problem	14/11/2018	
									A0709	Device Sensing Problem	14/11/2018	

CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	
CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	14/11/2018	
		F1001	Absence of Treatment	A0709	Device Sensing Problem	14/11/2018	
		F1905	Device Revision or Replacement	A0709	Electrical /Electronic Property Problem	14/11/2018	

								A0709	Device Sensing Problem	14/11/2018	
3148	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
									A0708	Power Problem	
3149	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
3150	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
3151	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
3152	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	
									A09	Output Problem	
									A090404	Output Above Specifications	
						F1905	Device Revision or Replacement		A07	Electrical /Electronic Property Problem	
									A0709	Device Sensing Problem	

				A09	Output Problem			
				A090404	Output Above Specifications			
CT12726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT12727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT12750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT12866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT12985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT13001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT13002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT13006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT13007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT1314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
CT1321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			
				A090404	Output Above Specifications			
		F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
				A0709	Device Sensing Problem			
				A09	Output Problem			

					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
							F1905	Device Revision or Replacement	A07 A0709 A09 A090404	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
							F1905	Device Revision or Replacement	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
							F1905	Device Revision or Replacement	A07 A0709 A09 A090404	Electrical /Electronic Property Problem Device Sensing Problem Output Problem Output Above Specifications		
3153	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
3154	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3155	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
3156	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
3157	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09 A090404	Output Problem Output Above Specifications		
3158	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
3159	2018	All other reportable incidents			CT258	Implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
							F1905	Device Revision or Replacement	A17 A01 A17	Compatibility Problem Patient Device Interaction Problem Compatibility Problem		
3160	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing		
3161	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem	31/01/2018	
3162	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A04 A0405	Material Integrity Problem Degraded	12/01/2018 12/01/2018	
3163	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3164	2018	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
3165	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3166	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
3167	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090404	Output Above Specifications	10/07/2018	
3168	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	10/07/2018	
3169	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/incallianes	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3170	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/incallianes	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3171	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	04/07/2018	
3172	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator					A0708	Power Problem	04/07/2018	
					CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT233	Surgical	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT2406	Implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT2985	Active	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT981	Single use	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
3173	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3174	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3175	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
									A07	Power Problem		
3176	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
									A26	Insufficient Device Problem Information		
3177	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/06/2018	
									A0708	Power Problem	27/06/2018	
3178	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/07/2017	
									A0709	Device Sensing Problem	27/07/2017	
3179	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic	A09	Output Problem	22/06/2018	

					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3181	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3182	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem		
									A090404	Output Above Specifications		
3183	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	06/11/2018	
									A0708	Power Problem	06/11/2018	
3184	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3185	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		

					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
									A09	Output Problem		
3186	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	25/10/2018	
									A0708	Power Problem	25/10/2018	
3187	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3188	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	30/03/2017	
									A0708	Power Problem	30/03/2017	
3189	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	27/06/2018	
									A0708	Power Problem	27/06/2018	
3190	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	12/07/2018	
									A0708	Power Problem	12/07/2018	
3191	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3192	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3193	2018	Unanticipated serious deterioration in state of health			CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
3194	2017	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem		
									A17	Compatibility Problem		
3195	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3196	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3187	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3198	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
3199	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3200	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
3201	2018	All other reportable incidents			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
3202	2018	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
3203	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/11/2018	
3204	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/11/2018	
3205	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	25/01/2018	
3206	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
3207	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and	F10	Inadequate/Inappropriate Treatment or Diagnostic	A07	Electrical /Electronic Property Problem		

						associated devices		Exposure	A0709	Device Sensing Problem		
						CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	
						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem	
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem	
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem	
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem	
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem	
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem	
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem	
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem	
3208	2018	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem	
3209	2017	TBD				CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem	
3210	2018	All other reportable incidents				CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Device Sensing Problem	
3211	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A09	Output Problem	24/10/2018
						CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/10/2018
						CT1150	Defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	24/10/2018
						CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT233	Surgical	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT2406	Implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT2407	Active implantable	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT2985	Active	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT3001	Implantable metal	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT314	Electrically powered	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT449	Generators and associated devices	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
						CT981	Single use	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018
						CT983	Surgical invasive	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018
3212	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	
3213	2018	All other reportable incidents				CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A0708	Power Problem	
3214	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A23	Use of Device Problem	
								F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	
						CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
								F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	
						CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
									A07	Electrical /Electronic Property Problem		

						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem		
3216	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A17	Compatibility Problem	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0902	Display or Visual Feedback Problem	
3217	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3218	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0514	Thrombosis/Thrombus	A0708	Power Problem		
							F1905	Device Revision or Replacement	A05	Mechanical Problem	21/11/2017	
									A0501	Detachment of Device or Device Component	21/11/2017	
3219	2018	All other reportable incidents			CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A05	Mechanical Problem	21/11/2017	
									A0501	Detachment of Device or Device Component	21/11/2017	
3220	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	25/06/2018	
									A0708	Power Problem	25/06/2018	
3221	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
3222	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Power Problem		
									A0709	Electrical /Electronic Property Problem	09/10/2018	
3223	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem	09/10/2018	
									A0708	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3224	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem		
									A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3225	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
3226	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3227	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3228	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
									A26	Insufficient Device Problem Information	25/02/2015	
3229	2018	All other reportable incidents			CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A12	Connection Problem		
									A23	Use of Device Problem		
3230	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A11	Computer Software Problem		
									A1102	Application Program Problem		
3231	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
3232	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
3233	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3234	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3235	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3236	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	06/07/2018	
3237	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	05/07/2018	
3238	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	21/11/2018	
3239	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	21/11/2018	
3240	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	01/11/2018	
							F1905	Device Revision or Replacement	A17	Compatibility Problem	01/11/2018	
									A01	Patient Device Interaction Problem	01/11/2018	
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
							F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018	
									A17	Compatibility Problem	01/11/2018	
					CT1150	Defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	01/11/2018	
							F1905	Device Revision or Replacement	A17	Compatibility Problem	01/11/2018	
									A01	Patient Device Interaction Problem	01/11/2018	
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
							F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018	
									A17	Compatibility Problem	01/11/2018	
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	01/11/2018	
							F1905	Device Revision or Replacement	A17	Compatibility Problem	01/11/2018	
									A01	Patient Device Interaction Problem	01/11/2018	
					CT233	Surgical	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
							F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018	
									A17	Compatibility Problem	01/11/2018	
					CT2406	Implantable	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	01/11/2018	
							F1905	Device Revision or Replacement	A17	Compatibility Problem	01/11/2018	
									A01	Patient Device Interaction Problem	01/11/2018	
					CT2407	Active implantable	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
									A01	Patient Device Interaction Problem	01/11/2018	
									A17	Compatibility Problem	01/11/2018	

						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
								A01	Patient Device Interaction Problem	01/11/2018		
						F1905	Device Revision or Replacement	A17	Compatibility Problem	01/11/2018		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	01/11/2018	
						F1905	Device Revision or Replacement	A17	Compatibility Problem	01/11/2018		
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	01/11/2018	
						F1905	Device Revision or Replacement	A17	Compatibility Problem	01/11/2018		
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	01/11/2018	
						F1905	Device Revision or Replacement	A17	Compatibility Problem	01/11/2018		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT2985	Active	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT3001	Implantable metal	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT314	Electrically powered	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT449	Generators and associated devices	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT981	Single use	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
					CT983	Surgical invasive	E1906	Unspecified Infection	A17	Compatibility Problem	01/11/2018	
						F1905	Device Revision or Replacement	A01	Patient Device Interaction Problem	01/11/2018		
								A17	Compatibility Problem	01/11/2018		
3241	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1104	Computer Operating System Problem	28/06/2018	
								A13	Communication or Transmission Problem	28/06/2018		
								A26	Insufficient Device Problem Information	28/06/2018		
3242	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical/Electronic Property Problem	17/08/2017	
3243	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	17/08/2017	
3244	2017	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Electrical/Electronic Property Problem	05/09/2017	
								A09	Power Problem	05/09/2017		
								A090404	Output Problem			
								A1104	Output Above Specifications			
3245	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Computer Operating System Problem		
								A090404	Output Problem			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Above Specifications		
								A090404	Output Problem			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Above Specifications		
								A090404	Output Problem			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Above Specifications		
								A090404	Output Problem			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Above Specifications		
								A090404	Output Problem			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Above Specifications		
								A090404	Output Problem			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Above Specifications		
								A09	Output Problem			

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
									A09	Output Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
									A09	Output Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
									A09	Output Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
									A09	Output Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
									A090404	Output Above Specifications		
3246	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	
									A09	Output Problem	02/07/2018	
									A090404	Output Above Specifications	02/07/2018	
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	02/07/2018	
									A0709	Device Sensing Problem	02/07/2018	

									A090404	Output Above Specifications		
3248	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3249	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
3250	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
3251	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem		
3252	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Electrical /Electronic Property Problem		
3253	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Power Problem	11/04/2017	
3254	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information	15/09/2010	
3255	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	11/04/2017	
3256	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	11/04/2017	
3257	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	26/06/2018	
3258	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information	26/06/2018	
3259	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
3260	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3261	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A09	Output Problem		
3262	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
3263	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3264	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Electrical /Electronic Property Problem	20/02/2018	
3265	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Power Problem	20/02/2018	
3266	2018	All other reportable incidents			CT258	Implantable defibrillators	E2401	Insufficient Information	A0709	Device Sensing Problem		
3267	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/05/2018	
3268	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	27/05/2018	
3269	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	07/11/2018	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem	07/11/2018	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem	07/11/2018	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	07/11/2018	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications	07/11/2018	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
									A13	Communication or Transmission Problem		
3270	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
									A07	Electrical /Electronic Property Problem		
3271	2018	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
3272	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
3273	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem		
									A0709	Electrical /Electronic Property Problem		
3274	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Power Problem		
									A0709	Electrical /Electronic Property Problem		
3275	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Device Sensing Problem		
									A0709	Electrical /Electronic Property Problem		

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3276	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem	21/04/2017	
3277	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	21/04/2017	
3278	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem	14/02/2018	
3279	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	29/10/2018	
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
3280	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Electrical /Electronic Property Problem		
3281	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Power Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
3282	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
3283	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070908	Failure to Sense		
3284	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F05	Delay to Treatment/ Therapy	A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
3285	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A11	Computer Software Problem		
									A1102	Application Program Problem		
3286	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
3287	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		

					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3288	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3289	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
									A26	Insufficient Device Problem Information		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
									A26	Insufficient Device Problem Information		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
									A26	Insufficient Device Problem Information		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		

				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A0713	Defibrillation/Stimulation Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic	A07	Electrical /Electronic Property Problem				

3300	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem							
									A0709	Device Sensing Problem							
					3301	2018	All other reportable incidents			CT1258	Implantable defibrillators	E1906	Unspecified Infection	A26	Insufficient Device Problem Information		
						3302	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/07/2018
					3303	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator					A0708	Power Problem		23/07/2018
										CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
														A0709	Device Sensing Problem		
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07						Electrical /Electronic Property Problem							
				A0709						Device Sensing Problem							

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3304	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/02/2018	
									A0708	Power Problem	07/02/2018	
3305	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3306	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3307	2017	Death			CT258	Implantable defibrillators	F21	Unexpected Deterioration	A26	Insufficient Device Problem Information		
3308	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
									A26	Insufficient Device Problem Information		
3309	2017	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3310	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	05/07/2018	
									A0708	Power Problem	05/07/2018	
3311	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/07/2018	
									A0708	Power Problem	13/07/2018	
3312	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	10/11/2018	
									A0708	Power Problem	10/11/2018	
3313	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3314	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
									A1102	Application Program Problem		
3315	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3316	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A0708	Power Problem		
3317	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3318	2018	TBD			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3319	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3320	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3321	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
3322	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/03/2018	
3323	2018	All other reportable incidents	4/2/70	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	08/03/2018	
3324	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	24/10/2017	
3325	2018	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	24/02/2018	
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3331	2018	All other reportable incidents			CT258	Implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
3332	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
3333	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3334	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3335	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
3336	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F05	Delay to Treatment/ Therapy	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT233	Surgical	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT2407	Active implantable	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT2985	Active	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT314	Electrically powered	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT981	Single use	F05	Delay to Treatment/ Therapy	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
3337	2017	TBD			CT258	Implantable defibrillators			A07	Electrical /Electronic Property Problem		
3338	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3339	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3340	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
3341	2018	Death			CT258	Implantable defibrillators	F21	Unexpected Deterioration	A07	Electrical /Electronic Property Problem		
3342	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0709	Device Sensing Problem		
3343	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	12/07/2018	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	12/07/2018	
									A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	13/11/2018	
									A07	Electrical /Electronic Property Problem	13/11/2018	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	13/11/2018	
									A07	Electrical /Electronic Property Problem	13/11/2018	
									A0709	Device Sensing Problem	13/11/2018	
3346	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3347	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A12	Connection Problem	05/02/2018	
3348	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/10/2018	
									A0708	Power Problem	23/10/2018	
3349	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3350	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT233	Surgical	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT2406	Implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT2985	Active	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	

					CT3001	Implantable metal	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0708	Power Problem	27/11/2018	
									A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT981	Single use	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	27/11/2018	
									A0708	Power Problem	27/11/2018	
3351	2017	All other reportable incidents	33552	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		

					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404 A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A09	Output Above Specifications Electrical /Electronic Property Problem Device Sensing Problem Output Problem		
3352	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3353	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3354	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT233	Surgical	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT2406	Implantable	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT2985	Active	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT981	Single use	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	07/05/2018	
3355	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
3356	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
							F14	Prolonged Episode of Care	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3357	2018	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
3358	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	14/02/2018	
3359	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem	22/02/2018	

	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3361	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT1145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		

					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
3362	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
3363	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090404	Output Above Specifications		
3364	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	08/11/2018	
3365	2017	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	08/11/2018	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
3366	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0907	No Device Output		
3367	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
3368	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
3369	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1102	Application Program Problem		
									A26	Insufficient Device Problem Information		
3370	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A11	Computer Software Problem		
3371	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1102	Application Program Problem		
									A16	Protective Measures Problem		
									A1602	Fail-Safe Problem		
3372	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	22/11/2018	
3373	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/11/2018	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3374	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3375	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	09/07/2018	
3376	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	09/07/2018	
3377	2017	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information	25/07/2018	
3378	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
3379	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		

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				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
CT2985	Active	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
CT3001	Implantable metal	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F15	Recognized Device or Procedural Complication	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
CT3006	Implantable inorganic material	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem	20/09/2022	20/09/2022
				A0709	Device Sensing Problem	20/09/2022	20/09/2022
				A070909	Overensing	20/09/2022	20/09/2022

						F15	Recognized Device or Procedural Complication	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	20/09/2022 20/09/2022 20/09/2022
					CT3007	Implantable ceramic	E2401	Insufficient Information	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F15	Recognized Device or Procedural Complication	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
					CT314	Electrically powered	E2401	Insufficient Information	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F15	Recognized Device or Procedural Complication	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F15	Recognized Device or Procedural Complication	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
					CT449	Generators and associated devices	E2401	Insufficient Information	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F15	Recognized Device or Procedural Complication	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
					CT981	Single use	E2401	Insufficient Information	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F15	Recognized Device or Procedural Complication	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
					CT983	Surgical invasive	E2401	Insufficient Information	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
						F15	Recognized Device or Procedural Complication	A07 A0709 A070909	Electrical /Electronic Property Problem Device Sensing Problem Oversensing	20/09/2022 20/09/2022 20/09/2022	
3400	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	05/03/2018 05/03/2018
3401	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem	
3402	2018	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem	
3403	2018	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203 A26	Defective Device Insufficient Device Problem Information	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203 A26	Defective Device Insufficient Device Problem Information	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203 A26	Defective Device Insufficient Device Problem Information	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203 A26	Defective Device Insufficient Device Problem Information	

					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Defective Device		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A2033	Insufficient Device Problem Information		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Defective Device		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A2033	Insufficient Device Problem Information		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A26	Defective Device		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A2033	Insufficient Device Problem Information		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A26	Defective Device		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A2033	Insufficient Device Problem Information		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A26	Defective Device		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A2033	Insufficient Device Problem Information		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A26	Defective Device		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A2033	Insufficient Device Problem Information		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A26	Defective Device		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A2033	Insufficient Device Problem Information		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A26	Defective Device		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A2033	Insufficient Device Problem Information		
3404	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	29/11/2018	
3405	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	29/11/2018	
3406	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Geometrical /Electronic Property Problem		
3407	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem		
3408	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	02/08/2018	
3409	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	02/08/2018	
3410	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	05/03/2018	
3411	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	22/02/2018	
3412	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070802	Intermittent Loss of Power		
3413	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/12/2018	
3414	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem	07/12/2018	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

3415	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
3416	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		

					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3417	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	18/05/2017	
									A0708	Power Problem	18/05/2017	
3418	2017	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	18/07/2017	
									A0708	Power Problem	18/07/2017	
3419	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3420	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A01	Patient Device Interaction Problem	22/02/2018	
									A17	Compatibility Problem	22/02/2018	
									A01	Patient Device Interaction Problem	22/02/2018	
									A17	Compatibility Problem	22/02/2018	
3421	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3422	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0722	Impedance Problem		
									A072201	High Impedance		
3423	2018	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
					CT1150	Defibrillators	E2401	Insufficient Information	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	E2401	Insufficient Information	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
					CT233	Surgical	E2401	Insufficient Information	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
					CT2406	Implantable	E2401	Insufficient Information	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
					CT2407	Active implantable	E2401	Insufficient Information	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		

CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
				A09	Output Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090404	Output Above Specifications		
				A26	Insufficient Device Problem Information		
CT263	Cardiographs and associated devices	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT2985	Active	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT3001	Implantable metal	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT3006	Implantable inorganic material	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT3007	Implantable ceramic	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT314	Electrically powered	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT321	Long-term surgical invasive	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT449	Generators and associated devices	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		
CT981	Single use	E2401	Insufficient Information	A09	Output Problem		
				A090404	Output Above Specifications		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A26	Insufficient Device Problem Information		
				A09	Output Problem		

								Exposure	A090404	Output Above Specifications		
					CT983	Surgical invasive	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
									A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A090404	Output Above Specifications		
									A26	Insufficient Device Problem Information		
3424	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3425	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	07/08/2018	
									A0708	Power Problem	07/08/2018	
3426	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A09	Output Problem		
									A0904	Energy Output Problem		
									A090402	Failure to Deliver Energy		
							F1905	Device Revision or Replacement	A09	Output Problem		
									A0904	Energy Output Problem		
									A090402	Failure to Deliver Energy		
3427	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	30/07/2018	
									A0708	Power Problem	30/07/2018	
3428	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0722	Impedance Problem		
									A072201	High Impedance		
3429	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	11/07/2018	
									A0708	Power Problem		
3430	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	11/07/2018	
									A0709	Device Sensing Problem		
3431	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F14	Prolonged Episode of Care	A09	Output Problem		
					CT1147	Defibrillators and associated devices	F14	Prolonged Episode of Care	A09	Energy Output Problem		
					CT1150	Defibrillators	F14	Prolonged Episode of Care	A0904	Output Problem		
									A09	Output Problem		
					CT141	Electrodes/Leads and associated devices	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT145	Cardiovascular devices	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT233	Surgical	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT2406	Implantable	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT2407	Active implantable	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT263	Cardiographs and associated devices	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT2726	Physiological monitoring/measuring devices	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT2727	Active implant devices/ancillaries	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT2866	Implantable cardiac electrical stimulators	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT2985	Active	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT3001	Implantable metal	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT3002	Implantable synthetic polymer	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT3006	Implantable inorganic material	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT3007	Implantable ceramic	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT314	Electrically powered	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT321	Long-term surgical invasive	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT449	Generators and associated devices	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT981	Single use	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
					CT983	Surgical invasive	F14	Prolonged Episode of Care	A0904	Energy Output Problem		
									A09	Output Problem		
3432	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F14	Prolonged Episode of Care	A05	Mechanical Problem		
					CT1147	Defibrillators and associated devices	F14	Prolonged Episode of Care	A0510	Retraction Problem		
					CT1150	Defibrillators	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT141	Electrodes/Leads and associated devices	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT145	Cardiovascular devices	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT233	Surgical	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT2406	Implantable	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		

					CT2407	Active implantable	F14	Prolonged Episode of Care	A05	Mechanical Problem		
					CT258	Implantable defibrillators	F14	Prolonged Episode of Care	A0510	Retraction Problem		
									A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT263	Cardiographs and associated devices	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT2726	Physiological monitoring/measuring devices	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT2727	Active implant devices/ancillaries	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT2866	Implantable cardiac electrical stimulators	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT2985	Active	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT3001	Implantable metal	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT3002	Implantable synthetic polymer	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT3006	Implantable inorganic material	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT3007	Implantable ceramic	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT314	Electrically powered	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT321	Long-term surgical invasive	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT449	Generators and associated devices	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT981	Single use	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
					CT983	Surgical invasive	F14	Prolonged Episode of Care	A05	Mechanical Problem		
									A0510	Retraction Problem		
3433	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem		
									A0708	Power Problem		
3434	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
3435	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/08/2018	
									A0709	Device Sensing Problem	14/08/2018	
3436	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	15/05/2017	
									A0708	Power Problem	15/05/2017	
3437	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	23/05/2017	
									A0708	Power Problem	23/05/2017	
3438	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3439	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
3440	2018	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	29/11/2018	
									A0711	Interrogation Problem	29/11/2018	
									A071102	Failure to Interrogate	29/11/2018	
3441	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	24/12/2018	
									A0705	Battery Problem	24/12/2018	
									A070504	Premature Discharge of Battery	24/12/2018	
3442	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07	Electrical /Electronic Property Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07 A0713 A071302	Electrical /Electronic Property Problem Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation		
3443	2017	TBD			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3444	2017	TBD	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
3445	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3446	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Power Problem		
3447	2017	TBD	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0709	Electrical /Electronic Property Problem Device Sensing Problem		
3448	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/08/2018	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/08/2018	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/08/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/08/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/08/2018	
					CT233	Surgical	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/08/2018	
					CT2406	Implantable	F1905	Device Revision or Replacement	A07 A0708	Electrical /Electronic Property Problem Power Problem	09/08/2018	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	09/08/2018	

					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT2985	Active	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT981	Single use	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0708	Power Problem	09/08/2018	
									A07	Electrical /Electronic Property Problem	09/08/2018	
3449	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators			A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
3450	2018	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
3451	2017	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
3452	2017	Unanticipated serious deterioration in state of health			CT258	Implantable defibrillators	F21	Unexpected Deterioration	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
3453	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
3454	2018	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
3455	2018	All other reportable incidents			CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0708	Power Problem		
									A07	Electrical /Electronic Property Problem		
3456	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		
									A0709	Device Sensing Problem		
									A09	Output Problem		
									A090404	Output Above Specifications		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A07	Electrical /Electronic Property Problem		

					CT145	Cardiovascular devices	F26	No Health Consequences or Impact	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT13001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
3468	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
							F14	Prolonged Episode of Care	A090801	Signal Artifact/Noise			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
							F14	Prolonged Episode of Care	A090801	Signal Artifact/Noise			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
							F14	Prolonged Episode of Care	A090801	Signal Artifact/Noise			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
							F14	Prolonged Episode of Care	A090801	Signal Artifact/Noise			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
							F14	Prolonged Episode of Care	A090801	Signal Artifact/Noise			
					CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
							F14	Prolonged Episode of Care	A090801	Signal Artifact/Noise			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
							F14	Prolonged Episode of Care	A090801	Signal Artifact/Noise			
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
							F14	Prolonged Episode of Care	A090801	Signal Artifact/Noise			

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						F15	Recognized Device or Procedural Complication	A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing	
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A0712	Pacing Problem		
						F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing	
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A0712	Pacing Problem		
						F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A0712	Pacing Problem		
						F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing	
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A0712	Pacing Problem		
						F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing	
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A0712	Pacing Problem		
						F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
3471	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	
							F26	No Health Consequences or Impact	A1107	Data Problem	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem	

3473	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A0705	Battery Problem																
									A070504	Premature Discharge of Battery																
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022	05/01/2022														
									A070504	Premature Discharge of Battery	05/01/2022	05/01/2022														
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022														
									A070504	Premature Discharge of Battery	05/01/2022	05/01/2022														
							F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022														
									A070504	Premature Discharge of Battery	05/01/2022	05/01/2022														
							CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022	05/01/2022												
											A070504	Premature Discharge of Battery	05/01/2022	05/01/2022												
									F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022												
											A070504	Premature Discharge of Battery	05/01/2022	05/01/2022												
									F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022												
											A070504	Premature Discharge of Battery	05/01/2022	05/01/2022												
									CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022	05/01/2022										
													A070504	Premature Discharge of Battery	05/01/2022	05/01/2022										
											F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022										
													A070504	Premature Discharge of Battery	05/01/2022	05/01/2022										
											F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022										
													A070504	Premature Discharge of Battery	05/01/2022	05/01/2022										
											CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022	05/01/2022								
															A070504	Premature Discharge of Battery	05/01/2022	05/01/2022								
													F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022								
															A070504	Premature Discharge of Battery	05/01/2022	05/01/2022								
													F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022								
															A070504	Premature Discharge of Battery	05/01/2022	05/01/2022								
													CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022	05/01/2022						
																	A070504	Premature Discharge of Battery	05/01/2022	05/01/2022						
															F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022						
																	A070504	Premature Discharge of Battery	05/01/2022	05/01/2022						
															F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022						
																	A070504	Premature Discharge of Battery	05/01/2022	05/01/2022						
															CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022	05/01/2022				
																			A070504	Premature Discharge of Battery	05/01/2022	05/01/2022				
																	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022				
																			A070504	Premature Discharge of Battery	05/01/2022	05/01/2022				
																	F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022				
																			A070504	Premature Discharge of Battery	05/01/2022	05/01/2022				
																	CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022	05/01/2022		
																					A070504	Premature Discharge of Battery	05/01/2022	05/01/2022		
																			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022		
																					A070504	Premature Discharge of Battery	05/01/2022	05/01/2022		
																			F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022		
																					A070504	Premature Discharge of Battery	05/01/2022	05/01/2022		
																			CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022	05/01/2022
																							A070504	Premature Discharge of Battery	05/01/2022	05/01/2022
																					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022
																							A070504	Premature Discharge of Battery	05/01/2022	05/01/2022
																					F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022
																							A070504	Premature Discharge of Battery	05/01/2022	05/01/2022
																					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
		A070504	Premature Discharge of Battery	05/01/2022	05/01/2022																					
F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022	05/01/2022																					
		A070504	Premature Discharge of Battery	05/01/2022	05/01/2022																					
F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022																					
		A070504	Premature Discharge of Battery	05/01/2022	05/01/2022																					
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022																	05/01/2022			
				A070504	Premature Discharge of Battery	05/01/2022																	05/01/2022			
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022																	05/01/2022			
				A070504	Premature Discharge of Battery	05/01/2022	05/01/2022																			
		F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022																			
				A070504	Premature Discharge of Battery	05/01/2022	05/01/2022																			
		CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022															05/01/2022			
						A070504	Premature Discharge of Battery	05/01/2022															05/01/2022			
				F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022															05/01/2022			
						A070504	Premature Discharge of Battery	05/01/2022	05/01/2022																	
				F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022																	
						A070504	Premature Discharge of Battery	05/01/2022	05/01/2022																	
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022													05/01/2022			
								A070504	Premature Discharge of Battery	05/01/2022													05/01/2022			
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022													05/01/2022			
								A070504	Premature Discharge of Battery	05/01/2022	05/01/2022															
						F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022															
								A070504	Premature Discharge of Battery	05/01/2022	05/01/2022															
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022											05/01/2022			
										A070504	Premature Discharge of Battery	05/01/2022											05/01/2022			
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022											05/01/2022			
										A070504	Premature Discharge of Battery	05/01/2022	05/01/2022													
								F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022													
										A070504	Premature Discharge of Battery	05/01/2022	05/01/2022													
								CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022									05/01/2022			
												A070504	Premature Discharge of Battery	05/01/2022									05/01/2022			
										F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022									05/01/2022			
												A070504	Premature Discharge of Battery	05/01/2022	05/01/2022											
										F1903	Device Explanation	A0705	Battery Problem	05/01/2022	05/01/2022											
												A070504	Premature Discharge of Battery	05/01/2022	05/01/2022											
										CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/01/2022							05/01/2022			
														A070504	Premature Discharge of Battery	05/01/2022							05/01/2022			
												F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/01/2022							05/01/2022			

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			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A070505	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
CT2726	Physiological monitoring/measuring devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
CT314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					A0705	Battery Problem	21/07/2021	21/07/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021	21/07/2021
					A070504	Premature Discharge of Battery	21/07/2021	21/07/2021

						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
								A0705	Battery Problem	21/07/2021	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					CT0981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/07/2021	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	21/07/2021	21/07/2021
								A070504	Premature Discharge of Battery	21/07/2021	21/07/2021
3483	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		
								A071302	Inappropriate/inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/inadequate Shock/Stimulation		
						F13	Mediagnosis/ Misclassification	A070909	Oversensing		

					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909	Oversensing			
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
3484	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT11150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT12726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/Inadequate Shock/Stimulation			

					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F13	Midagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F13	Midagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F13	Midagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F13	Midagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
3485	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A070909	Oversensing		
							F21	Unexpected Deterioration	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071204	No Pacing		
									A071204	Oversensing		
									A070909	No Pacing		
									A071204	Premature Discharge of Battery		
3486	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3487	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3488	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
3489	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3490	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A070910	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A070910	Undersensing		

CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT1150	Defibrillators	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT145	Cardiovascular devices	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT233	Surgical	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT2406	Implantable	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT2407	Active implantable	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT258	Implantable defibrillators	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT263	Cardiographs and associated devices	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT2726	Physiological monitoring/measuring devices	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A071202	Inaccurate Synchronization		

CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
CT2966	Implantable cardiac electrical stimulators			A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E0601	Arrhythmia	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT2985		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
CT2985	Active			A071202	Inaccurate Synchronization		
		E0601	Arrhythmia	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E0601	Arrhythmia	A070910	Undersensing		
CT3002	Implantable synthetic polymer			A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT3006	Implantable inorganic material	F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E0601	Arrhythmia	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
CT3007	Implantable ceramic			A071202	Inaccurate Synchronization		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT314	Electrically powered	E0601	Arrhythmia	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
CT321	Long-term surgical invasive			A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT449	Generators and associated devices	F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E0601	Arrhythmia	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
CT981	Single use			A071202	Inaccurate Synchronization		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A071202	Inaccurate Synchronization		
CT983	Surgical invasive	E0601	Arrhythmia	A070910	Undersensing		

							E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910 A071202	Inaccurate Synchronization Undersensing Inaccurate Synchronization		
							F08	Hospitalization or Prolonged Hospitalization	A070910 A071202	Undersensing Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A070910 A071202	Undersensing Inaccurate Synchronization		
3491	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing		
3492	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/07/2021	28/07/2021

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		F1905	Device Revision or Replacement	A0705	Battery Problem	27/09/2021	27/09/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
CT2750	Implantable cardiac electrical stimulators and associated devices			A0705	Battery Problem	27/09/2021	27/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
CT2985	Active			A0705	Battery Problem	27/09/2021	27/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
CT3002	Implantable synthetic polymer			A0705	Battery Problem	27/09/2021	27/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
CT3007	Implantable ceramic			A0705	Battery Problem	27/09/2021	27/09/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
CT314	Electrically powered			A0705	Battery Problem	27/09/2021	27/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
CT449	Generators and associated devices			A0705	Battery Problem	27/09/2021	27/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
				A0705	Battery Problem	27/09/2021	27/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/09/2021	27/09/2021

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
									A0705	Battery Problem	27/09/2021	27/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
									A0705	Battery Problem	27/09/2021	27/09/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
									A0705	Battery Problem	27/09/2021	27/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/09/2021	27/09/2021
									A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/09/2021	27/09/2021
									A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	27/09/2021	27/09/2021
									A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/09/2021	27/09/2021
									A070504	Premature Discharge of Battery	27/09/2021	27/09/2021
3494	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F13	Mid-diagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F13	Mid-diagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F13	Mid-diagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F13	Mid-diagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		

CT233	Surgical	F13	Misdiagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2406	Implantable	F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Misdiagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Misdiagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	F13	Misdiagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Misdiagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Misdiagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		

					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F19	Surgical Intervention		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F19	Surgical Intervention		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F19	Surgical Intervention		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F19	Surgical Intervention		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F19	Surgical Intervention		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification		A051201	Device Dislodged or Dislocated		
					A070909	Oversensing		

				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F12	Serious Injury/ Illness/ Impairment	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F13	Mediagnosis/ Misclassification	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F19	Surgical Intervention	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		

						F12	Serious injury/ illness/ Impairment	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
						F13	Misdiagnosis/ Misclassification	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
						F19	Surgical Intervention	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
				C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
						F12	Serious injury/ illness/ Impairment	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
						F13	Misdiagnosis/ Misclassification	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
						F19	Surgical Intervention	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
				C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
						F12	Serious injury/ illness/ Impairment	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
						F13	Misdiagnosis/ Misclassification	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
						F19	Surgical Intervention	A1301 A061201 A070909 A090801	Failure to Read Input Signal Device Dislodged or Dislocated Oversensing Signal Artifact/Noise			
3495	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1233	Surgical	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT12407	Active implantable	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1263	Cardiographs and associated devices	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT12727	Active implant devices/ancillaries	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT12866	Implantable cardiac electrical stimulators	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT13001	Implantable metal	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT13006	Implantable inorganic material	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1314	Electrically powered	F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1449	Generators and associated devices	F23	Unexpected Medical Intervention	A070909	Oversensing		

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
3496	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							A070504	Premature Discharge of Battery	27/08/2021	27/08/2021		
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							A070504	Premature Discharge of Battery	27/08/2021	27/08/2021		
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							A070504	Premature Discharge of Battery	27/08/2021	27/08/2021		
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							A070504	Premature Discharge of Battery	27/08/2021	27/08/2021		
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							A070504	Premature Discharge of Battery	27/08/2021	27/08/2021		
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							A070504	Premature Discharge of Battery	27/08/2021	27/08/2021		
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							A070504	Premature Discharge of Battery	27/08/2021	27/08/2021		
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							A070504	Premature Discharge of Battery	27/08/2021	27/08/2021		
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021					
		A070504	Premature Discharge of Battery	27/08/2021	27/08/2021							
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021					
		A070504	Premature Discharge of Battery	27/08/2021	27/08/2021							
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021					
		A070504	Premature Discharge of Battery	27/08/2021	27/08/2021							
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021					
		A070504	Premature Discharge of Battery	27/08/2021	27/08/2021							
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021					
		A070504	Premature Discharge of Battery	27/08/2021	27/08/2021							
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021					
		A070504	Premature Discharge of Battery	27/08/2021	27/08/2021							
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021					
				A070504	Premature Discharge of Battery	27/08/2021	27/08/2021					
CT2985		Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021				

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CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT2406	Implantable	F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT2407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT2726	Physiological monitoring/measuring devices	F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT3001	Implantable metal	F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT3002	Implantable synthetic polymer	F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
CT314	Electrically powered	F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A0508	Noise, Audible	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021

		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
				A070504	Premature Discharge of Battery		

3500	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator			F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/07/2021	12/07/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/07/2021	12/07/2021
3501	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact		A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
3502	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021

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							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/007/2021	3/007/2021
							F1905	Device Revision or Replacement	A070504	Battery Problem	3/007/2021	3/007/2021
									A070504	Premature Discharge of Battery	3/007/2021	3/007/2021
									A070504	Battery Problem	3/007/2021	3/007/2021
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									A070504	Battery Problem	3/007/2021	3/007/2021
									A070504	Premature Discharge of Battery	3/007/2021	3/007/2021

			Exposure					
CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
				A071302	Inappropriate/Inadequate Shock/Stimulation			
F08	Hospitalization or Prolonged Hospitalization			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		CT1145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
				A071302	Inappropriate/Inadequate Shock/Stimulation			
F08	Hospitalization or Prolonged Hospitalization			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		CT233	Surgical	E2104	Electric Shock	A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
				A071302	Inappropriate/Inadequate Shock/Stimulation			
F08	Hospitalization or Prolonged Hospitalization			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		CT2408	Implantable	E2104	Electric Shock	A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
F08	Hospitalization or Prolonged Hospitalization			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		CT2407	Active implantable	E2104	Electric Shock	A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
F08	Hospitalization or Prolonged Hospitalization			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						A070909	Overensing	
				E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
						A070909	Overensing	
F08	Hospitalization or Prolonged Hospitalization			A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A071302	Inappropriate/Inadequate Shock/Stimulation			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
						A071302	Inappropriate/Inadequate Shock/Stimulation	
F08	Hospitalization or Prolonged Hospitalization			A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A071302	Inappropriate/Inadequate Shock/Stimulation			

CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1905	Device Revision or Replacement	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	E2104	Electric Shock	A070909	Oversensing		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	E2104	Electric Shock	A070909	Oversensing		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	E2104	Electric Shock	A070909	Oversensing		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1905	Device Revision or Replacement	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	E2104	Electric Shock	A070909	Oversensing		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1905	Device Revision or Replacement	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	E2104	Electric Shock	A070909	Oversensing		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1905	Device Revision or Replacement	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
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								A070909	Oversensing		
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CT2406	Implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021

								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
3510	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT2726	Physiological monitoring/measuring devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2021	13/09/2021
										A070504	Premature Discharge of Battery	13/09/2021	13/09/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2021	13/09/2021

		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
				A072201	High Impedance		
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
		F26	No Health Consequences or Impact	A072201	High Impedance		
				A010402	Migration		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A072201	High Impedance		

3514	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator		F26	No Health Consequences or Impact	A010402	Migration		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A010402	Migration	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
3515	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	

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				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A010402	Migration		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E2104	Electric Shock	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	E2104	Electric Shock	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A010402	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Migration		
				A070909	Overensensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic	A010402	Migration		

			Exposure	A070909 A071302	Overensing Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
CT2985	Active	E2104	Electric Shock	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
CT3001	Implantable metal	E2104	Electric Shock	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
CT3006	Implantable inorganic material	E2104	Electric Shock	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
CT3007	Implantable ceramic	E2104	Electric Shock	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A010402 A070909 A071302	Migration Overensing Inappropriate/Inadequate Shock/Stimulation			

					CT314	Electrically powered	E2104	Electric Shock	A010402	Migration		
									A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F2203	Imaging Required	A010402	Migration		
									A070909	Oversensing		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
									A070909	Oversensing		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
									A070909	Oversensing		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
									A070909	Oversensing		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/inadequate Shock/Stimulation		
									A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
3521	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

					CT3001	Implantable metal	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3522	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/08/2021	09/08/2021	
									A0705	Battery Problem	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/08/2021	09/08/2021
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/08/2021	09/08/2021	
									A070504	Premature Discharge of Battery	09/08/2021	09/08/2021

CT141	Electrodes/Leads and associated devices		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT145	Cardiovascular devices		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT233	Surgical		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT2406	Implantable		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT2407	Active implantable		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT258	Implantable defibrillators		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT263	Cardiographs and associated devices		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT2726	Physiological monitoring/measuring devices		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT2727	Active implant devices/ancillaries		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT2750	Implantable cardiac electrical stimulators and associated devices		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT2866	Implantable cardiac electrical stimulators		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT2985	Active		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT3001	Implantable metal		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT3002	Implantable synthetic polymer		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	
CT3006	Implantable inorganic material		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	
					A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	

						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
3525	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2021	02/03/2021
3526	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
3527	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/04/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/04/2022	26/04/2022

					C1286	Implantable defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C12727	Active implant devices/ancillaries	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C12750	Implantable cardiac electrical stimulators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C12866	Implantable cardiac electrical stimulators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C12985	Active	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C13001	Implantable metal	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C13002	Implantable synthetic polymer	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C13006	Implantable inorganic material	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C13007	Implantable ceramic	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C1314	Electrically powered	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C1321	Long-term surgical invasive	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C1449	Generators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C1981	Single use	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
					C1983	Surgical invasive	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	26/04/2022 26/04/2022 26/04/2022	26/04/2022 26/04/2022 26/04/2022
3528	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	C11010	Cardiovascular physiology analysis/mapping devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C11147	Defibrillators and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C11150	Defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C1141	Electrodes/Leads and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C1145	Cardiovascular devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C1233	Surgical	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C12406	Implantable	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C12407	Active implantable	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C1258	Implantable defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C1263	Cardiographs and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C12726	Physiological monitoring/measuring devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		
					C12727	Active implant devices/ancillaries	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712 A070910	Undersensing Pacing Problem Undersensing		

		F26	No Health Consequences or Impact	A070909	Oversensing		
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2985	Active	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Oversensing		
									A070909	Oversensing		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
3530	2021	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070101	Failure to Capture	26/07/2021	26/07/2021
									A0712	Pacing Problem	26/07/2021	26/07/2021
							F12	Serious Injury/ Illness/ Impairment	A13	Communication or Transmission Problem	26/07/2021	26/07/2021
									A070101	Failure to Capture	26/07/2021	26/07/2021
									A0712	Pacing Problem	26/07/2021	26/07/2021
									A13	Communication or Transmission Problem	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070101	Failure to Capture	26/07/2021	26/07/2021
									A0712	Pacing Problem	26/07/2021	26/07/2021
									A13	Communication or Transmission Problem	26/07/2021	26/07/2021
3531	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
									A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/07/2021	30/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021
									A0705	Battery Problem	30/07/2021	30/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/07/2021	30/07/2021

								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT1314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT149	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT1981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
					CT1983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								F26	No Health Consequences or Impact	A070910	Undersensing		
3535	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
					CT1150	Defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
					CT145	Cardiovascular devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
							E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
					CT233	Surgical	E0601	Arrhythmia	A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
					CT2406	Implantable	E0601	Arrhythmia	A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			
					CT2407	Active implantable	E0601	Arrhythmia	A0711	Interrogation Problem			
									A071201	Failure to Convert Rhythm			

				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
		F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
CT258	Implantable defibrillators	E0601	Arrhythmia	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT2985	Active	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT3001	Implantable metal	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT3006	Implantable inorganic material	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT3007	Implantable ceramic	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F23	Unexpected Medical Intervention	A0711	Interrogation Problem		
				A071201	Failure to Convert Rhythm		
CT314	Electrically powered	E0601	Arrhythmia	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0711	Interrogation Problem		

										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						E2403	No Clinical Signs, Symptoms or Conditions			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
						F23	Unexpected Medical Intervention			A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT321	Long-term surgical invasive	E0601	Arrhythmia		A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						E2403	No Clinical Signs, Symptoms or Conditions			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F23	Unexpected Medical Intervention			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT449	Generators and associated devices	E0601	Arrhythmia		A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						E2403	No Clinical Signs, Symptoms or Conditions			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F23	Unexpected Medical Intervention			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT981	Single use	E0601	Arrhythmia		A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						E2403	No Clinical Signs, Symptoms or Conditions			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F23	Unexpected Medical Intervention			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT983	Surgical invasive	E0601	Arrhythmia		A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						E2403	No Clinical Signs, Symptoms or Conditions			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F23	Unexpected Medical Intervention			A0711	Interrogation Problem		
										A071201	Failure to Convert Rhythm		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
3536	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	04/08/2021	04/08/2021
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery	04/08/2021	04/08/2021
3537	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
										A0705	Battery Problem	13/08/2021	13/08/2021
							F1903	Device Explanation		A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
										A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1903	Device Explanation		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1903	Device Explanation		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1903	Device Explanation		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1903	Device Explanation		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1903	Device Explanation		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1903	Device Explanation		A0705	Battery Problem	13/08/2021	13/08/2021
										A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	13/08/2021	13/08/2021

				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
				A0705	Battery Problem	13/08/2021	13/08/2021
				A070504	Premature Discharge of Battery	13/08/2021	13/08/2021

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1903	Device Explanation	A0705	Battery Problem	13/08/2021	13/08/2021
									A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/08/2021	13/08/2021
									A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1903	Device Explanation	A0705	Battery Problem	13/08/2021	13/08/2021
									A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
3538	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801 A070909 A071302 A090801	Signal Artifact/Noise Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A090801	Signal Artifact/Noise		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A090801	Signal Artifact/Noise		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT981	Single use	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
3539	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F26	No Health Consequences or Impact	A070909	Overensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		

						CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT449	Generators and associated devices	E2403	No Health Consequences or Impact	A070909	Oversensing		
								F26	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT981	Single use	F26	No Health Consequences or Impact	A070909	Oversensing		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT983	Surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
3540	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
								F1903	Device Explanation	A0705	Battery Problem	23/08/2021	23/08/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/08/2021	23/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2021	23/08/2021

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		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A070910	Undersensing		
CT2406	Implantable	E060102	Atrial Fibrillation	A0712	Pacing Problem		
				A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT2407	Active implantable	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT258	Implantable defibrillators	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT2727	Active implant devices/ancillaries	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT2866	Implantable cardiac electrical stimulators	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT2985	Active	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT3001	Implantable metal	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT3002	Implantable synthetic polymer	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT3006	Implantable inorganic material	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT3007	Implantable ceramic	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT314	Electrically powered	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT321	Long-term surgical invasive	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		
CT449	Generators and associated devices	E060102	Atrial Fibrillation	A070910	Undersensing		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070910	Undersensing		
				A0712	Pacing Problem		

					CT981	Single use	E060102	Atrial Fibrillation	A070910	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT983	Surgical invasive	E060102	Atrial Fibrillation	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070910	Undersensing		
3542	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
3543	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		

					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07054 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
3544	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07054 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022 11/08/2022	11/08/2022 11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	11/08/2022 11/08/2022	11/08/2022 11/08/2022

					CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/04/2021	28/04/2021
					CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/04/2021	28/04/2021
							F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/04/2021	28/04/2021
							F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/04/2021	28/04/2021
							F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/04/2021	28/04/2021
							F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/04/2021	28/04/2021
							F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/04/2021	28/04/2021
							F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/04/2021	28/04/2021
							F26	No Health Consequences or Impact	A070909	Oversensing	28/04/2021	28/04/2021
3546	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/09/2021	10/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/09/2021	10/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/09/2021	10/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/09/2021	10/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/09/2021	10/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/09/2021	10/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/09/2021	10/09/2021

						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			E2403	No Clinical Signs, Symptoms or Conditions		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F05	Delay to Treatment/ Therapy		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			E2403	No Clinical Signs, Symptoms or Conditions		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F05	Delay to Treatment/ Therapy		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			E2403	No Clinical Signs, Symptoms or Conditions		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F05	Delay to Treatment/ Therapy		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021

						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
						A070910	Undersensing	27/07/2021	27/07/2021
			F05	Delay to Treatment/ Therapy		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
						A070910	Undersensing	27/07/2021	27/07/2021
			F05	Delay to Treatment/ Therapy		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			CT2408	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
						A070910	Undersensing	27/07/2021	27/07/2021
			F05	Delay to Treatment/ Therapy		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
						A072201	High Impedance	27/07/2021	27/07/2021
			F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
						A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
						A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021

CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
		F05	Delay to Treatment/ Therapy	A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
		F1905	Device Revision or Replacement	A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
A070910	Undersensing			27/07/2021	27/07/2021		
F2203	Imaging Required	A070910	Undersensing	27/07/2021	27/07/2021		
		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021		
		A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021		
		A072201	High Impedance	27/07/2021	27/07/2021		
		A070910	Undersensing	27/07/2021	27/07/2021		
F2306	Resuscitation	A070910	Undersensing	27/07/2021	27/07/2021		
		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021		
		A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021		
		A072201	High Impedance	27/07/2021	27/07/2021		
		A070910	Undersensing	27/07/2021	27/07/2021		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
		F05	Delay to Treatment/ Therapy	A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
		F1905	Device Revision or Replacement	A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
A072201	High Impedance			27/07/2021	27/07/2021		
F2203	Imaging Required	A070910	Undersensing	27/07/2021	27/07/2021		
		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021		
		A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021		
		A072201	High Impedance	27/07/2021	27/07/2021		
		A070910	Undersensing	27/07/2021	27/07/2021		
F2306	Resuscitation	A070910	Undersensing	27/07/2021	27/07/2021		
		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021		
		A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021		
		A072201	High Impedance	27/07/2021	27/07/2021		
		A070910	Undersensing	27/07/2021	27/07/2021		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
		F05	Delay to Treatment/ Therapy	A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
		F1905	Device Revision or Replacement	A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
A072201	High Impedance			27/07/2021	27/07/2021		
F2203	Imaging Required	A070910	Undersensing	27/07/2021	27/07/2021		
		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021		
		A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021		
		A072201	High Impedance	27/07/2021	27/07/2021		
		A070910	Undersensing	27/07/2021	27/07/2021		
F2306	Resuscitation	A070910	Undersensing	27/07/2021	27/07/2021		
		A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021		
		A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021		
		A072201	High Impedance	27/07/2021	27/07/2021		
		A070910	Undersensing	27/07/2021	27/07/2021		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	High Impedance	27/07/2021	27/07/2021
				A072201	Undersensing	27/07/2021	27/07/2021
				A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
				A07113	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
				A072201	High Impedance	27/07/2021	27/07/2021
				A070910	Undersensing	27/07/2021	27/07/2021

							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				CT2985	Active		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F05	Delay to Treatment/ Therapy		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				CT3001	Implantable metal		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F05	Delay to Treatment/ Therapy		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F1905	Device Revision or Replacement		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F2203	Imaging Required		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F2306	Resuscitation		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				CT3002	Implantable synthetic polymer		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F05	Delay to Treatment/ Therapy		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Simulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021

							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
			F1905	Device Revision or Replacement			A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
			F2203	Imaging Required			A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
			F2306	Resuscitation			A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
			CT3008	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F05	Delay to Treatment/ Therapy	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F1905	Device Revision or Replacement	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F2203	Imaging Required	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F2306	Resuscitation	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
			CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F05	Delay to Treatment/ Therapy	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F1905	Device Revision or Replacement	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F2203	Imaging Required	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F2306	Resuscitation	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
			CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F05	Delay to Treatment/ Therapy	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
							A072201	High Impedance	27/07/2021	27/07/2021
					F1905	Device Revision or Replacement	A070910	Undersensing	27/07/2021	27/07/2021
							A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
							A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021

F2203	Imaging Required	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F2306	Resuscitation	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F05	Delay to Treatment/ Therapy	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F1905	Device Revision or Replacement	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F2203	Imaging Required	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F2306	Resuscitation	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F05	Delay to Treatment/ Therapy	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F1905	Device Revision or Replacement	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F2203	Imaging Required	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F2306	Resuscitation	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F05	Delay to Treatment/ Therapy	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F1905	Device Revision or Replacement	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021
F2203	Imaging Required	A072201	High Impedance	2/7/07/2021	2/7/07/2021
		A070910	Undersensing	2/7/07/2021	2/7/07/2021
		A071201	Failure to Convert Rhythm	2/7/07/2021	2/7/07/2021
		A0713	Defibrillation/Stimulation Problem	2/7/07/2021	2/7/07/2021

							F2306	Resuscitation	A070910	Undersensing	27/07/2021	27/07/2021
									A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
									A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
									A072201	High Impedance	27/07/2021	27/07/2021
				CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	27/07/2021	27/07/2021	27/07/2021
									A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
									A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
									A072201	High Impedance	27/07/2021	27/07/2021
						F05	Delay to Treatment/ Therapy	A070910	Undersensing	27/07/2021	27/07/2021	27/07/2021
									A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
									A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
									A072201	High Impedance	27/07/2021	27/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	27/07/2021	27/07/2021	27/07/2021
									A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
									A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
									A072201	High Impedance	27/07/2021	27/07/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic exposure	A070910	Undersensing	27/07/2021	27/07/2021	27/07/2021
									A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
									A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
									A072201	High Impedance	27/07/2021	27/07/2021
						F1905	Device Revision or Replacement	A070910	Undersensing	27/07/2021	27/07/2021	27/07/2021
									A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
									A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
									A072201	High Impedance	27/07/2021	27/07/2021
						F2203	Imaging Required	A070910	Undersensing	27/07/2021	27/07/2021	27/07/2021
									A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
									A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
									A072201	High Impedance	27/07/2021	27/07/2021
						F2306	Resuscitation	A070910	Undersensing	27/07/2021	27/07/2021	27/07/2021
									A071201	Failure to Convert Rhythm	27/07/2021	27/07/2021
									A0713	Defibrillation/Stimulation Problem	27/07/2021	27/07/2021
									A072201	High Impedance	27/07/2021	27/07/2021
3548	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3549	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
									A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022	
									A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022	
									A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022	
									A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
					CT1147	Defibrillators and associated devices	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022

				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
				A0705	Battery Problem	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
				A0705	Battery Problem	03/05/2022	03/05/2022
CT1150	Defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
				A0705	Battery Problem	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
				A0705	Battery Problem	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT141	Electrodes/Leads and associated devices	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT145	Cardiovascular devices	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT233	Surgical	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT2406	Implantable	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT2407	Active implantable	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT258	Implantable defibrillators	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT263	Cardiographs and associated devices	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT2726	Physiological monitoring/measuring devices	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT2727	Active implant devices/ancillaries	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E020201	Anxiety	A0705	Battery Problem	03/05/2022	03/05/2022
				A070504	Premature Discharge of Battery	03/05/2022	03/05/2022

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								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	03/05/2022	03/05/2022
										A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
										A0705	Battery Problem	03/05/2022	03/05/2022
										A070504	Premature Discharge of Battery	03/05/2022	03/05/2022
3550	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2727	Active implant devices/incinerates	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
		F26	No Health Consequences or Impact	A072201	High Impedance								
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
		F26	No Health Consequences or Impact	A072201	High Impedance								
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
		F26	No Health Consequences or Impact	A072201	High Impedance								
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
		F26	No Health Consequences or Impact	A072201	High Impedance								
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
		F26	No Health Consequences or Impact	A072201	High Impedance								
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
		F26	No Health Consequences or Impact	A072201	High Impedance								
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
CT981	Single use	F26	No Health Consequences or Impact	A072201	High Impedance								
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
		F26	No Health Consequences or Impact	A072201	High Impedance								
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
		F26	No Health Consequences or Impact	A072201	High Impedance								
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance								
3551	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Overensing	13/10/2021	13/10/2021	
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	13/10/2021	13/10/2021	
							A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021			
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	13/10/2021	13/10/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing	13/10/2021	13/10/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
						F1905	Device Revision or Replacement	A070909	Overensing	13/10/2021	13/10/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
						F2203	Imaging Required	A070909	Overensing	13/10/2021	13/10/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
						F23	Unexpected Medical Intervention	A070909	Overensing	13/10/2021	13/10/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Overensing	13/10/2021	13/10/2021	
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	13/10/2021	13/10/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
							F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	13/10/2021	13/10/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing	13/10/2021	13/10/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
							F1905	Device Revision or Replacement	A070909	Overensing	13/10/2021	13/10/2021	
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
						F2203	Imaging Required	A070909	Overensing	13/10/2021	13/10/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
						F23	Unexpected Medical Intervention	A070909	Overensing	13/10/2021	13/10/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensing	13/10/2021	13/10/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	13/10/2021	13/10/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
							F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	13/10/2021	13/10/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing	13/10/2021	13/10/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
									A070909	Overensing	13/10/2021	13/10/2021	

CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A070909	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021	13/10/2021
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
CT145	Cardiovascular devices	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021	13/10/2021
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
CT1233	Surgical	E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021	13/10/2021
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
CT12406	Implantable	F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
CT12407	Active implantable	F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021	13/10/2021
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
CT1258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021

CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
				A070909	Overensensing	13/10/2021	13/10/2021

		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
			F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
			F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F23	Unexpected Medical Intervention	A071302	Oversensing	13/10/2021	13/10/2021	
			A070909	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
			F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F23	Unexpected Medical Intervention	A071302	Oversensing	13/10/2021	13/10/2021	
			A070909	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
			F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
			F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
			F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F2203	Imaging Required	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F23	Unexpected Medical Intervention	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/10/2021	13/10/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/10/2021	13/10/2021	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/10/2021	13/10/2021	
	F1905	Device Revision or Replacement	A070909	Oversensing	13/10/2021	13/10/2021	

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CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT12726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
F1905			Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT12750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
F1905			Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT12985	Active	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
F1905			Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT13002	Implantable synthetic polymer	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
F1905			Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT13007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
F1905			Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT1321	Long-term surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
F1905			Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT1981	Single use	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
F1905			Device Revision or Replacement	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2021	25/08/2021
				A070504	Premature Discharge of Battery	25/08/2021	25/08/2021

3554	2021	All other reportable incidents	35552	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2021	25/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
									A0705	Battery Problem	15/09/2021	15/09/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
									A070504	Premature Discharge of Battery	15/09/2021	15/09/2021

						F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021
								A0705	Battery Problem	15/09/2021	15/09/2021
3555	2021	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/08/2021
								A071201	Failure to Convert Rhythm	10/08/2021	10/08/2021
								A072202	Low Impedance	10/08/2021	10/08/2021
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/08/2021	10/08/2021
							F02	Death	A070504	Premature Discharge of Battery	10/08/2021
								A071201	Failure to Convert Rhythm	10/08/2021	10/08/2021
								A072202	Low Impedance	10/08/2021	10/08/2021
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/08/2021	10/08/2021
3556	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/07/2022
								A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/07/2022
								A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/07/2022
								A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
3557	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Atrial fibrillation	A070603	Failure to Charge	12/11/2021
								A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
								A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
								A090805	Incorrect Measurement	12/11/2021	12/11/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021
								A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
								A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
								A090805	Incorrect Measurement	12/11/2021	12/11/2021
							F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021
								A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
								A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
								A090805	Incorrect Measurement	12/11/2021	12/11/2021
					CT1147	Defibrillators and associated devices	E0601	Atrial fibrillation	A070603	Failure to Charge	12/11/2021
								A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
								A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
								A090805	Incorrect Measurement	12/11/2021	12/11/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021
								A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
								A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021

				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
CT1150	Defibrillators	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
CT145	Cardiovascular devices	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
CT233	Surgical	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
CT2406	Implantable	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
CT2407	Active implantable	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
CT258	Implantable defibrillators	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
		F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021

		F1901	Additional Surgery	A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
CT3006	Implantable inorganic material	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
CT3007	Implantable ceramic	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
CT314	Electrically powered	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
CT321	Long-term surgical invasive	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
CT449	Generators and associated devices	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
CT981	Single use	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
CT983	Surgical invasive	E0601	Arrhythmia	A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
				A070603	Failure to Charge	12/11/2021	12/11/2021
				A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021
				A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021
				A090805	Incorrect Measurement	12/11/2021	12/11/2021
	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
	F1901	Additional Surgery	A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	
			A070603	Failure to Charge	12/11/2021	12/11/2021	
			A071201	Failure to Convert Rhythm	12/11/2021	12/11/2021	
			A071301	Failure to Deliver Shock/Stimulation	12/11/2021	12/11/2021	
			A090805	Incorrect Measurement	12/11/2021	12/11/2021	

			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
CT2407	Active implantable	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
CT258	Implantable defibrillators	E2403		No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
CT263	Cardiographs and associated devices	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
CT2726	Physiological monitoring/measuring devices	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
CT2727	Active implant devices/ancillaries	E2403		No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
CT2866	Implantable cardiac electrical stimulators	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
CT2985	Active	E2403		No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
CT3001	Implantable metal	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
CT3002	Implantable synthetic polymer	E2403		No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
CT3006	Implantable inorganic material	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
CT3007	Implantable ceramic	E2403		No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
CT314	Electrically powered	E2403		No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
CT321	Long-term surgical invasive	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
		F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
		F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					A0705	Battery Problem	10/02/2022	10/02/2022
CT449	Generators and associated devices	E2403		No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022
					A070504	Premature Discharge of Battery	10/02/2022	10/02/2022

								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022
								F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	10/02/2022	10/02/2022
										A070504	Battery Problem	10/02/2022	10/02/2022
										A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022	10/02/2022
										A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022	10/02/2022
										A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022	10/02/2022
										A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/02/2022	10/02/2022	10/02/2022
										A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/02/2022	10/02/2022	10/02/2022
										A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/02/2022	10/02/2022	10/02/2022
										A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
										A070504	Premature Discharge of Battery	10/02/2022	10/02/2022
3560	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT12408	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT12728	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021
					CT12750	Implantable cardiac electrical stimulators and	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2021	29/09/2021	29/09/2021

						associated devices				A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
										A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	29/09/2021	29/09/2021
										A070504	Premature Discharge of Battery	29/09/2021	29/09/2021
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	14/09/2021	14/09/2021
										A070504	Premature Discharge of Battery	14/09/2021	14/09/2021

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		F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2021	05/08/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2021	05/08/2021
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2021	05/08/2021
CT2727	Active implant devices/ancillaries	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2021	05/08/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2021	05/08/2021
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2021	05/08/2021
CT2985	Active	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2021	05/08/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2021	05/08/2021
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2021	05/08/2021
CT3006	Implantable inorganic material	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2021	05/08/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2021	05/08/2021
CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2021	05/08/2021
CT321	Long-term surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2021	05/08/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2021	05/08/2021
CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2021	05/08/2021
CT983	Surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
				A0705	Battery Problem	05/08/2021	05/08/2021
				A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2021	05/08/2021

									A070504	Premature Discharge of Battery	05/08/2021	05/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem			
								A070504	Premature Discharge of Battery	05/08/2021	05/08/2021	05/08/2021
3563	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1233	Surgical	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT12406	Implantable	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT12407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A071302 A1301	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
C12726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
C12727	Active implant devices/incineraries	E2104	Electric Shock	A1301 A070909 A071302	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A1301 A070909 A071302	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
C12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
C12866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A1301 A070909 A071302	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
C12985	Active	E2104	Electric Shock	A1301 A070909 A071302	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A1301 A070909 A071302	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A1301 A070909 A071302	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		

CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT1983	Surgical invasive	E2104	Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	Electric Shock	A079008	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A079009	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A079009	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/04/2022	01/04/2022
									A070504	Premature Discharge of Battery	01/04/2022	01/04/2022

					A070504	Premature Discharge of Battery	3/05/2022	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
					A070504	Premature Discharge of Battery	3/05/2022	3/05/2022
CT233	Surgical			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	3/05/2022
					A070504	Premature Discharge of Battery	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	3/05/2022
					A070504	Premature Discharge of Battery	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A0705	Battery Problem	3/05/2022
CT2406	Implantable			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
CT2407	Active implantable			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A0705	Battery Problem	3/05/2022
CT258	Implantable defibrillators			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
CT263	Cardiographs and associated devices			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
CT2726	Physiological monitoring/measuring devices			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
CT2727	Active implant devices/ancillaries			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A0705	Battery Problem	3/05/2022
					A070504	Premature Discharge of Battery	3/05/2022	3/05/2022
CT2750	Implantable cardiac electrical stimulators and associated devices			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
CT2866	Implantable cardiac electrical stimulators			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	3/05/2022
					A0705	Battery Problem	3/05/2022	3/05/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	3/05/202

CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A071102	Failure to Interrogate	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
		F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A071102	Failure to Interrogate	24/03/2022	24/03/2022
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A071102	Failure to Interrogate	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
		F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A071102	Failure to Interrogate	24/03/2022	24/03/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
CT2727	Active implant devices(ancillaries)	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A071102	Failure to Interrogate	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
		F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A071102	Failure to Interrogate	24/03/2022	24/03/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A071102	Failure to Interrogate	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
		F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A071102	Failure to Interrogate	24/03/2022	24/03/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071206	Pacing Asynchronously	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
		F1901	Additional Surgery	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	24/03/2022	24/03/2022
				A071206	Pacing Asynchronously	24/03/2022	24/03/2022
		F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2022	24/03/2022
				A070504	Premature Discharge of Battery	24/03/2022	24/03/2022

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					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/02/2022	06/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/02/2022	06/02/2022
									A070504	Premature Discharge of Battery	06/02/2022	06/02/2022
3590	2021	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F02	Death	A070910	Undersensing		
									A070909	Oversensing		
									A070910	Undersensing		
3581	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT1147	Defibrillators and associated devices	F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT1150	Defibrillators	F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT2750	Implantable cardiac electrical stimulators and	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022

						associated devices	F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	25/03/2022	25/03/2022
3582	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A0705	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A0705	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A0705	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A0705	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A0705	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A0705	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
									A070504	Battery Problem		

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				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				

					CT3006	Implantable inorganic material	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
3585	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		

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					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
									A0705	Battery Problem	13/08/2021	13/08/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
									A0705	Battery Problem	13/08/2021	13/08/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/08/2021	13/08/2021
									A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/08/2021	13/08/2021
									A070504	Premature Discharge of Battery	13/08/2021	13/08/2021
3587	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

							A0712	Pacing Problem		
					F26	No Health Consequences or Impact	A070909	Oversensing		
					E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							A070909	Oversensing		
					F26	No Health Consequences or Impact	A0712	Pacing Problem		
							A070909	Oversensing		
							A0712	Pacing Problem		
					E0602	Cardiac Arrest	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					F02	Death	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					F2306	Resuscitation	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					E0602	Cardiac Arrest	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					F02	Death	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					F2306	Resuscitation	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					E0602	Cardiac Arrest	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					F02	Death	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					F2306	Resuscitation	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					E0602	Cardiac Arrest	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
					A072201		A070909	High Impedance	06/08/2021	06/08/2021
					F02	Death	A070909	Oversensing	06/08/2021	06/08/2021
							A071201	Failure to Convert Rhythm	06/08/2021	06/

C12407	Active implantable	E0602	Cardiac Arrest	A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
		F02	Death	A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
		F2306	Resuscitation	A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
C1258	Implantable defibrillators	E0602	Cardiac Arrest	A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
		F02	Death	A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
		F2306	Resuscitation	A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
C1263	Cardiographs and associated devices	E0602	Cardiac Arrest	A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
		F02	Death	A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
		F2306	Resuscitation	A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
C12726	Physiological monitoring/measuring devices	E0602	Cardiac Arrest	A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
		F02	Death	A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
		F2306	Resuscitation	A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
C12727	Active implant devices/ancillaries	E0602	Cardiac Arrest	A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
		F02	Death	A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
		F2306	Resuscitation	A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
C12750	Implantable cardiac electrical stimulators and associated devices	E0602	Cardiac Arrest	A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
		F02	Death	A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
		F2306	Resuscitation	A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
C12866	Implantable cardiac electrical stimulators	E0602	Cardiac Arrest	A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
		F02	Death	A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
		F2306	Resuscitation	A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
C12985	Active	E0602	Cardiac Arrest	A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
				A072201	High Impedance	06/08/2021	06/08/2021
				A070909	Overensing	06/08/2021	06/08/2021
				A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021

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						F2306	Resuscitation	A070909	Oversensing	06/08/2021	06/08/2021
								A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
								A072201	High Impedance	06/08/2021	06/08/2021
				CT981	Single use	E0602	Cardiac Arrest	A070909	Oversensing	06/08/2021	06/08/2021
								A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
								A072201	High Impedance	06/08/2021	06/08/2021
						F02	Death	A070909	Oversensing	06/08/2021	06/08/2021
								A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
								A072201	High Impedance	06/08/2021	06/08/2021
						F2306	Resuscitation	A070909	Oversensing	06/08/2021	06/08/2021
								A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
								A072201	High Impedance	06/08/2021	06/08/2021
				CT983	Surgical invasive	E0602	Cardiac Arrest	A070909	Oversensing	06/08/2021	06/08/2021
								A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
								A072201	High Impedance	06/08/2021	06/08/2021
						F02	Death	A070909	Oversensing	06/08/2021	06/08/2021
								A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
								A072201	High Impedance	06/08/2021	06/08/2021
						F2306	Resuscitation	A070909	Oversensing	06/08/2021	06/08/2021
								A071201	Failure to Convert Rhythm	06/08/2021	06/08/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	06/08/2021	06/08/2021
								A072201	High Impedance	06/08/2021	06/08/2021
3589	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022
								Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/03/2022	28/03/2022
3590	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070910	Undersensing	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F02	Death	A070910	Undersensing		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
3591	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022
								Additional Surgery	A070504	Premature Discharge of Battery	13/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/09/2022	13/09/2022
								Additional Surgery	A070504	Premature Discharge of Battery	13/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
								Additional Surgery	A070504	Premature Discharge of Battery	13/09/2022
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022

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					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
									A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
									A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
									A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
									A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
									A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
									A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
									A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/09/2022	13/09/2022
									A070504	Premature Discharge of Battery	13/09/2022	13/09/2022
3592	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/09/2022	13/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
									A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
									A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
									A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
									A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
									A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
									A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021

CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
				A0705	Battery Problem	18/08/2021	18/08/2021
				A070504	Premature Discharge of Battery	18/08/2021	18/08/2021

						F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
								A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
					CT081	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
								A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
								A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
								A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
					CT083	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2021	18/08/2021
								A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/08/2021	18/08/2021
								A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	18/08/2021	18/08/2021
								A070504	Premature Discharge of Battery	18/08/2021	18/08/2021
3593	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1147	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT141	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT145	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT233	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT2406	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT2407	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT263	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT2726	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT2727	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F1903	Device Explanation	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT2750	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
								A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021

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						CT258	Implantable defibrillators	E2403	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT2727	Active implant devices/ancillaries	F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	12/04/2022	12/04/2022		
3599	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators		E0601	Arrhythmia	A070909	Oversensing				
										A071204	No Pacing				
										A12	Connection Problem				
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
										A071204	No Pacing				
										A12	Connection Problem				
										A070909	Oversensing				
										A071204	No Pacing				
										A12	Connection Problem				
3600	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022		
										A070504	Premature Discharge of Battery	13/07/2022	13/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022		
										A070504	Premature Discharge of Battery	13/07/2022	13/07/2022		
								F1903	Device Explanation	A0705	Battery Problem	13/07/2022	13/07/2022		
										A070504	Premature Discharge of Battery	13/07/2022	13/07/2022		
								CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
												A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
										F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022
												A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
F1903	Device Explanation	A0705	Battery Problem	13/07/2022	13/07/2022										
		A070504	Premature Discharge of Battery	13/07/2022	13/07/2022										
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022								
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022								
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022								
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022								
		F1903	Device Explanation	A0705	Battery Problem	13/07/2022	13/07/2022								
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022								
		CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
				F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
F1903	Device Explanation			A0705	Battery Problem	13/07/2022	13/07/2022								
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022								
CT145	Cardiovascular devices			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
				F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
		F1903	Device Explanation	A0705	Battery Problem	13/07/2022	13/07/2022								
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022								
		CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
				F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
F1903	Device Explanation			A0705	Battery Problem	13/07/2022	13/07/2022								
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022								
CT2406	Implantable			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
				F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
		F1903	Device Explanation	A0705	Battery Problem	13/07/2022	13/07/2022								
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022								
		CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
				F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
F1903	Device Explanation			A0705	Battery Problem	13/07/2022	13/07/2022								
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022								
CT258	Implantable defibrillators			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022						
						A070504	Premature Discharge of Battery	13/07/2022	13/07/2022						
				F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022						

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					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/09/2021	09/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/09/2021	09/09/2021
									A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
3604	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/08/2021	19/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021

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						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/08/2021
								A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	19/08/2021	19/08/2021
								A070504	Premature Discharge of Battery	19/08/2021	19/08/2021
3605	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A070909	Oversensing		
								A090801	Signal Artifact/Noise		
								A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A070909	Oversensing		
								A090801	Signal Artifact/Noise		
								A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A070909	Oversensing		
								A090801	Signal Artifact/Noise		
								A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A070909	Oversensing		
								A090801	Signal Artifact/Noise		
								A1301	Failure to Read Input Signal		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A070909	Oversensing		
								A090801	Signal Artifact/Noise		
								A1301	Failure to Read Input Signal		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A070909	Oversensing		
								A090801	Signal Artifact/Noise		
								A1301	Failure to Read Input Signal		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
								A1301	Failure to Read Input Signal		

					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3607	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT1150	Defibrillators	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT141	Electrodes/Leads and associated devices	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT145	Cardiovascular devices	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT233	Surgical	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT2406	Implantable	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		

				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2407	Active implantable	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E060110	Ventricular Fibrillation	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E060110	Ventricular Fibrillation	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT3001	Implantable metal	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E060110	Ventricular Fibrillation	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT3007	Implantable ceramic	E060110	Ventricular Fibrillation	A070101	Failure to Capture		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		

				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
				A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
				A070504	Premature Discharge of Battery	27/01/2022	27/01/2022

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
									A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
									A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
									A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
									A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
									A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
									A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
									A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2022	27/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/01/2022	27/01/2022
									A070504	Premature Discharge of Battery	27/01/2022	27/01/2022
3611	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT1150	Defibrillators	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT145	Cardiovascular devices	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT233	Surgical	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT2406	Implantable	E2402	Appropriate Clinical Signs, Symptoms and Conditions	A0709	Device Sensing Problem		

				Term/Code not Available	A071301	Failure to Deliver Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
				A071301	Failure to Deliver Shock/Stimulation				
CT2407	Active implantable	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT258	Implantable defibrillators	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT2727	Active implant devices/ancillaries	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT2750	Implantable cardiac electrical stimulators and associated devices	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT2866	Implantable cardiac electrical stimulators	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT2985	Active	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT3001	Implantable metal	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT3002	Implantable synthetic polymer	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT3006	Implantable inorganic material	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT3007	Implantable ceramic	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
		E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation				
				A0709	Device Sensing Problem				
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation				
CT314	Electrically powered	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A0709	Device Sensing Problem				
				A071301	Failure to Deliver Shock/Stimulation				

								E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A071301	Device Sensing Problem		
						CT321	Long-term surgical invasive	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A071301	Failure to Deliver Shock/Stimulation		
								E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A071301	Device Sensing Problem		
						CT449	Generators and associated devices	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A071301	Failure to Deliver Shock/Stimulation		
								E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A071301	Device Sensing Problem		
						CT981	Single use	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A071301	Failure to Deliver Shock/Stimulation		
								E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation		
								F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A071301	Device Sensing Problem		
						CT983	Surgical invasive	E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A071301	Failure to Deliver Shock/Stimulation		
								E2403	No Clinical Signs, Symptoms or Conditions	A071301	Device Sensing Problem		
								F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A071301	Device Sensing Problem		
3612	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0112	Dizziness	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F23	Unexpected Medical Intervention	A070909	Oversensing		
3613	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/1/1/2021		2/1/1/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021
								F1903	Device Explanation	A070504	Premature Discharge of Battery	2/1/1/2021	2/1/1/2021

					CT3002	Implantable synthetic polymer	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	21/11/2021 21/11/2021 21/11/2021	21/11/2021 21/11/2021 21/11/2021
					CT3006	Implantable inorganic material	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	21/11/2021 21/11/2021 21/11/2021	21/11/2021 21/11/2021 21/11/2021
					CT3007	Implantable ceramic	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	21/11/2021 21/11/2021 21/11/2021	21/11/2021 21/11/2021 21/11/2021
					CT314	Electrically powered	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	21/11/2021 21/11/2021 21/11/2021	21/11/2021 21/11/2021 21/11/2021
					CT321	Long-term surgical invasive	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	21/11/2021 21/11/2021 21/11/2021	21/11/2021 21/11/2021 21/11/2021
					CT449	Generators and associated devices	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	21/11/2021 21/11/2021 21/11/2021	21/11/2021 21/11/2021 21/11/2021
					CT981	Single use	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	21/11/2021 21/11/2021 21/11/2021	21/11/2021 21/11/2021 21/11/2021
					CT983	Surgical invasive	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	21/11/2021 21/11/2021 21/11/2021	21/11/2021 21/11/2021 21/11/2021
3614	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT1150	Defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT145	Cardiovascular devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT233	Surgical	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2406	Implantable	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2407	Active implantable	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT258	Implantable defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2727	Active implant devices/ancillaries	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2985	Active	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT3001	Implantable metal	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT3002	Implantable synthetic polymer	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT3006	Implantable inorganic material	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT3007	Implantable ceramic	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT314	Electrically powered	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT321	Long-term surgical invasive	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT449	Generators and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT981	Single use	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT983	Surgical invasive	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
3615	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT1150	Defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

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					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1905	Device Revision or Replacement	A070504	Battery Problem	13/10/2021	13/10/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	13/10/2021	13/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1905	Device Revision or Replacement	A070504	Battery Problem	13/10/2021	13/10/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	13/10/2021	13/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1905	Device Revision or Replacement	A070504	Battery Problem	13/10/2021	13/10/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1905	Device Revision or Replacement	A070504	Battery Problem	13/10/2021	13/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1905	Device Revision or Replacement	A070504	Battery Problem	13/10/2021	13/10/2021
3021	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/09/2021	14/09/2021

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									A071204	No Pacing	18/04/2022	18/04/2022
3626	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	18/04/2022	18/04/2022
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
3627	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		

								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A072201	High Impedance		
								A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A072201	High Impedance		
								A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A072201	High Impedance		
								A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A072201	High Impedance		
								A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A072201	High Impedance		
								A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A072201	High Impedance		
								A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A072201	High Impedance		
3628	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A070909	Oversensing		
								A0712	Pacing Problem		
3629	2021	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		

		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2806	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT981	Single use	E2104	Electric Shock	A070909	Oversensing		

		F1905	Device Revision or Replacement	A0705	Battery Problem	24/09/2021	24/09/2021
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT1141	Electrodes/Leads and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021
				A0705	Battery Problem	24/09/2021	24/09/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2021	24/09/2021

3635	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
									A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/08/2021	27/08/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021

						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
										A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	27/08/2021	27/08/2021
										A070504	Premature Discharge of Battery	27/08/2021	27/08/2021
3636	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
						CT11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
						CT11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
						CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
						CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
						CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2021	06/10/2021
										A070504	Premature Discharge of Battery	06/10/2021	06/10/2021

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							F1905	Device Revision or Replacement	A070504 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	08/10/2021 06/10/2021 06/10/2021	06/10/2021 06/10/2021 06/10/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	06/10/2021 06/10/2021	06/10/2021 06/10/2021
3637	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	28/09/2021 28/09/2021	28/09/2021 28/09/2021

				A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F1903	Device Explanation	A070505	Battery Problem	19/11/2021	19/11/2021
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F1903	Device Explanation	A070505	Battery Problem	19/11/2021	19/11/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F1903	Device Explanation	A070505	Battery Problem	19/11/2021	19/11/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	19/11/2021	19/11/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021

						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021					
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						F1903	Device Explanation	A0705	Battery Problem	19/11/2021	19/11/2021							
								A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021					
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						F1903	Device Explanation	A0705	Battery Problem	19/11/2021	19/11/2021							
								A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021					
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						F1903	Device Explanation	A0705	Battery Problem	19/11/2021	19/11/2021							
								A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021					
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						F1903	Device Explanation	A0705	Battery Problem	19/11/2021	19/11/2021							
								A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021					
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						F1903	Device Explanation	A0705	Battery Problem	19/11/2021	19/11/2021							
								A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021					
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						F1903	Device Explanation	A0705	Battery Problem	19/11/2021	19/11/2021							
								A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021					
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						F1903	Device Explanation	A0705	Battery Problem	19/11/2021	19/11/2021							
								A070504	Premature Discharge of Battery	19/11/2021	19/11/2021							
						3639	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
											F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021		
													A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
											F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021		
													A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
											F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021		
													A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
											F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021		
													A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
											F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
											F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021		
													A070504	Premature Discharge of Battery	28/10/2021	28/10/2021		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021						
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021								
					F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021								
							A070504	Premature Discharge of Battery	28/10/2021	28/10/2021								
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021						
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021								
					F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021								
							A070504	Premature Discharge of Battery	28/10/2021	28/10/2021								
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021						
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021								
							A070504	Premature Discharge of Battery	28/10/2021	28/10/2021								
						F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021							

CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
CT1226	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
CT1250	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
				A0705	Battery Problem	28/10/2021	28/10/2021
				A070504	Premature Discharge of Battery	28/10/2021	28/10/2021

							F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
									A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/10/2021	28/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/10/2021	28/10/2021
									A070504	Premature Discharge of Battery	28/10/2021	28/10/2021
3640	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/09/2021	28/09/2021
3641	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/05/2022	04/05/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/05/2022	04/05/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	04/05/2022	04/05/2022
									A070504	Premature Discharge of Battery	04/05/2022	04/05/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/05/2022	04/05/2022
									A070504	Premature Discharge of Battery	04/05/2022	04/05/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/05/2022	04/05/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/05/2022	04/05/2022
									A0705	Battery Problem	04/05/2022	04/05/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	04/05/2022	04/05/2022
									A070504	Premature Discharge of Battery	04/05/2022	04/05/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/05/2022	04/05/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/05/2022	04/05/2022
									A070504	Premature Discharge of Battery	04/05/2022	04/05/2022

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CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2022	07/05/2022
				A070602	Delayed Charge Time	07/05/2022	07/05/2022
				A07	Electrical /Electronic Property Problem	07/05/2022	07/05/2022

					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
3644	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070101	Failure to Capture		
									A070909	Oversensing		
									A070101	Failure to Capture		
									A070909	Oversensing		
3645	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

CT2406	Implantable	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

							E-Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A0712	Pacing Problem	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
3646	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							P23	Unexpected Medical Intervention	A23	Use of Device Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
									A23	Use of Device Problem	
3647	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
3648	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3649	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060110	Ventricular Fibrillation	A070910	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
					CT1150	Defibrillators	E060110	Ventricular Fibrillation	A070910	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E060110	Ventricular Fibrillation	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					CT145	Cardiovascular devices	E060110	Ventricular Fibrillation	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
					CT233	Surgical	E060110	Ventricular Fibrillation	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
					CT2406	Implantable	E060110	Ventricular Fibrillation	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					CT2407	Active implantable	E060110	Ventricular Fibrillation	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
					CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
					CT2727	Active implant devices/ancillaries	E060110	Ventricular Fibrillation	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202 A070910	Inaccurate Synchronization Undersensing		
		F15	Recognized Device or Procedural Complication	A071202 A070910	Inaccurate Synchronization Undersensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060110	Ventricular Fibrillation	A071202 A071202	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910 A071202	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A071202	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202 A070910	Undersensing Inaccurate Synchronization		
CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A071202	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910 A071202	Undersensing Inaccurate Synchronization		
CT2985	Active	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202 A070910	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202 A070910	Undersensing Inaccurate Synchronization		
CT3001	Implantable metal	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202 A070910	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202 A070910	Undersensing Inaccurate Synchronization		
CT3002	Implantable synthetic polymer	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A071202	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910 A071202	Undersensing Inaccurate Synchronization		
CT3006	Implantable inorganic material	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202 A070910	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202 A070910	Undersensing Inaccurate Synchronization		
CT3007	Implantable ceramic	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202 A070910	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202 A070910	Undersensing Inaccurate Synchronization		
CT314	Electrically powered	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A071202	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910 A071202	Undersensing Inaccurate Synchronization		
CT321	Long-term surgical invasive	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202 A070910	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202 A070910	Undersensing Inaccurate Synchronization		
CT449	Generators and associated devices	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202 A070910	Undersensing Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202 A070910	Undersensing Inaccurate Synchronization		
CT981	Single use	E060110	Ventricular Fibrillation	A071202 A070910	Undersensing Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202 A070910	Undersensing Inaccurate Synchronization		

[illegible]

[illegible]

CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	2001/2022	2001/2022
		P23	Unexpected Medical Intervention	A0705	Battery Problem	2001/2022	2001/2022
				A070504	Premature Discharge of Battery	2001/2022	2001/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2001/2022	2001/2022

CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2021	04/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2021	04/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2021	04/10/2021
CT981	Single use	E2403	Battery Problem	A0705	Battery Problem	04/10/2021	04/10/2021

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CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/09/2021	03/09/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	03/09/2021	03/09/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/09/2021	03/09/2021
CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT233	Surgical	F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT2407	Active implantable	F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021	10/09/2021
CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021

						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	10/09/2021
						F26	No Health Consequences or Impact	A0711	Interrogation Problem	10/09/2021	10/09/2021
3657	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	27/10/2021 27/10/2021	

CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT145	Cardiovascular devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT2407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021
				A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
				A0705	Battery Problem	13/10/2021	13/10/2021

3661	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/08/2021	26/08/2021		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	26/08/2021	26/08/2021		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/08/2021	26/08/2021		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	26/08/2021	26/08/2021		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/08/2021	26/08/2021		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	26/08/2021	26/08/2021		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing				
									F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
											A070910	Undersensing		
											A072201	High Impedance		

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/09/2021	09/09/2021
3665	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT1150	Defibrillators	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT141	Electrodes/Leads and associated devices	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT145	Cardiovascular devices	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT233	Surgical	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT2406	Implantable	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT2407	Active implantable	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT258	Implantable defibrillators	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT2727	Active implant devices/ancillaries	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT2866	Implantable cardiac electrical stimulators	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT2985	Active	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT3001	Implantable metal	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT3002	Implantable synthetic polymer	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT3006	Implantable inorganic material	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT3007	Implantable ceramic	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT314	Electrically powered	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT321	Long-term surgical invasive	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT449	Generators and associated devices	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT981	Single use	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
					CT983	Surgical invasive	E060103	Atrial Flutter	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
3666	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

			F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Overensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Overensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
CT314	Electrically powered	F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
CT983	Surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			

							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
3667	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/04/2022	28/04/2022
									A070504	Premature Discharge of Battery	28/04/2022	28/04/2022
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2022	28/04/2022

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					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2022	05/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/07/2022	05/07/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/07/2022	05/07/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/07/2022	05/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2022	05/07/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/07/2022	05/07/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/07/2022	05/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2022	05/07/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/07/2022	05/07/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/07/2022	05/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2022	05/07/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/07/2022	05/07/2022
3669	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Overensing		
3670	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021

		F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2727	Active implant devices/ancillaries	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2985	Active	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT3006	Implantable inorganic material	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021

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					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/10/2021	27/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	27/10/2021	27/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/10/2021	27/10/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/10/2021	27/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/10/2021	27/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/10/2021	27/10/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	27/10/2021	27/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/10/2021	27/10/2021
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	27/10/2021	27/10/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/10/2021	27/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/10/2021	27/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/10/2021	27/10/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	27/10/2021	27/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/10/2021	27/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/10/2021	27/10/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/10/2021	27/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/10/2021	27/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/10/2021	27/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	27/10/2021	27/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/10/2021	27/10/2021
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	27/10/2021	27/10/2021
3674	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	21/10/2021	21/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	21/10/2021	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	21/10/2021	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	21/10/2021	21/10/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	21/10/2021	21/10/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	21/10/2021	21/10/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	21/10/2021	21/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021

CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A0705	Battery Problem	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021
				A070504	Premature Discharge of Battery	21/10/2021	21/10/2021

						F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021	21/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2021
							F26	No Health Consequences or Impact	A0705	Battery Problem	21/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2021
									A070504	Premature Discharge of Battery	21/10/2021
3675	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
3676	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	

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						C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	19/07/2022 19/07/2022 19/07/2022	19/07/2022 19/07/2022 19/07/2022
						F08	Hospitalization or Prolonged Hospitalization			A0705 A070504	Battery Problem Premature Discharge of Battery	19/07/2022 19/07/2022	19/07/2022 19/07/2022
						F1905	Device Revision or Replacement			A0705 A070504	Battery Problem Premature Discharge of Battery	19/07/2022 19/07/2022	19/07/2022 19/07/2022
						C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	19/07/2022 19/07/2022	19/07/2022 19/07/2022
						F08	Hospitalization or Prolonged Hospitalization			A0705 A070504	Battery Problem Premature Discharge of Battery	19/07/2022 19/07/2022	19/07/2022 19/07/2022
						F1905	Device Revision or Replacement			A0705 A070504	Battery Problem Premature Discharge of Battery	19/07/2022 19/07/2022	19/07/2022 19/07/2022
3680	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	C11010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C11147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C11150	Defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C1145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C1233	Surgical	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C12406	Implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C12407	Active implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C1258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C1263	Cardiographs and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C12726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C12727	Active implant devices/ancillaries	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					C12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		

							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
									A0705	Battery Problem	18/10/2021	18/10/2021

CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021
				A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
				A0705	Battery Problem	18/10/2021	18/10/2021

							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
									A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/10/2021	18/10/2021
									A070504	Premature Discharge of Battery	18/10/2021	18/10/2021
3682	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
3683	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022

		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	06/12/2022	06/12/2022
				A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	06/12/2022	06/12/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	06/12/2022	06/12/2022
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	06/12/2022	06/12/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	06/12/2022	06/12/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	06/12/2022	06/12/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	06/12/2022	06/12/2022
CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	06/12/2022	06/12/2022
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	06/12/2022	06/12/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022

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					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3134	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3088	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/06/2022	16/06/2022
									A070504	Premature Discharge of Battery	16/06/2022	16/06/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/06/2022	16/06/2022

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3689	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Atrial fibrillation	A071201	Failure to Convert Rhythm		
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
3690	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2022	06/12/2022
									A070504	Premature Discharge of Battery	06/12/2022	06/12/2022

					CT314	Electrically powered	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
3692	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
3693	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
3694	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT145	Cardiovascular devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT233	Surgical	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT2406	Implantable	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT2407	Active implantable	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		

					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A072201	High Impedance			
									A090801	Signal Artifact/Noise			
3695	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/04/2022		22/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/04/2022		22/04/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/04/2022		22/04/2022
3696	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			

						F26	No Health Consequences or Impact	A0705	Battery Problem			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
3697	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
								A0705	Battery Problem		14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021

CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021	14/10/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021	14/10/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021	14/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021	14/10/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021	14/10/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021	14/10/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021	14/10/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
				A0705	Battery Problem	14/10/2021	14/10/2021
				A070504	Premature Discharge of Battery	14/10/2021	14/10/2021

						F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021	14/10/2021
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021
								A0705	Battery Problem	14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/10/2021
								A0705	Battery Problem	14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021
								A0705	Battery Problem	14/10/2021	14/10/2021
					CT081	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021
								A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021
								A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021
								A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
					CT083	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/10/2021
								A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/10/2021
								A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	14/10/2021
								A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
3698	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/10/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	18/05/2022
3699	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	18/05/2022
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT1150	Defibrillators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT145	Cardiovascular devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT233	Surgical	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT2406	Implantable	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT2407	Active implantable	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
							F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A090805	Incorrect Measurement		
					CT2985	Active	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	

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3707	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT981	Single use	F1901	Additional Surgery	A070504	Premature Discharge of Battery	18/05/2022	18/05/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/05/2022	18/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	18/05/2022	18/05/2022
3708	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/05/2022	18/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	18/05/2022	18/05/2022
							E2403	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021

						F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/11/2021
								A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021
								A0705	Battery Problem	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021
								A0705	Battery Problem	10/11/2021	10/11/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021
								A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
37/09	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0605	Cardiac Tamponade	A24	No Apparent Device Problem	
							E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem	
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem	
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem	
							F1908	Prolonged Surgery	A24	No Apparent Device Problem	
					CT1147	Defibrillators and associated devices	E0605	Cardiac Tamponade	A24	No Apparent Device Problem	
							E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem	
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem	
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem	
							F1908	Prolonged Surgery	A24	No Apparent Device Problem	
					CT1150	Defibrillators	E0605	Cardiac Tamponade	A24	No Apparent Device Problem	
							E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem	
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem	
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem	
							F1908	Prolonged Surgery	A24	No Apparent Device Problem	
					CT1141	Electrodes/Leads and associated devices	E0605	Cardiac Tamponade	A24	No Apparent Device Problem	
							E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem	
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem	
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem	
							F1908	Prolonged Surgery	A24	No Apparent Device Problem	
					CT1145	Cardiovascular devices	E0605	Cardiac Tamponade	A24	No Apparent Device Problem	
							E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem	
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem	
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem	
							F1908	Prolonged Surgery	A24	No Apparent Device Problem	
					CT233	Surgical	E0605	Cardiac Tamponade	A24	No Apparent Device Problem	
							E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem	

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3710	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem		
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem		
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem		
							F1908	Prolonged Surgery	A24	No Apparent Device Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
3711	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Overensing		

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CT1226	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT12727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT12866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT12985	Active	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		

					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071302 A1301	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT981	Single use	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
3712	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/05/2022	23/05/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/05/2022	23/05/2022
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	23/05/2022	23/05/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2022	23/05/2022
3713	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device		
3714	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	21/06/2022 21/06/2022	22/06/2022 22/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/06/2022	22/06/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	21/06/2022 21/06/2022	22/06/2022 22/06/2022

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					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible							
						F26	No Health Consequences or Impact	A0508	Noise, Audible								
					3746	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
														A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
												F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
														A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
												F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
														A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
										CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
														A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
												F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
														A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
												F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
														A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
														A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
												F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
														A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
												F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021

CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT3002	Implantable synthetic polymer	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021

						F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021
								A0705	Battery Problem	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021
								A0705	Battery Problem	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/11/2021
								A0705	Battery Problem	08/11/2021	08/11/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021
								A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
3717	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	

						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
3718	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	24/05/2022	24/05/2022
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2022	24/05/2022	
										A070504	Premature Discharge of Battery	24/05/2022	24/05/2022

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							F26	No Health Consequences or Impact	A0908	Noise, Audible		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Noise, Audible		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
3720	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/11/2021	18/11/2021
									A070504	Premature Discharge of Battery	18/11/2021	18/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/11/2021	18/11/2021

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						F1903	Device Explanation	A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
								A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
					CT321	Long-term surgical invasive		A0705	Battery Problem	15/06/2022	15/06/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
						F1903	Device Explanation	A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
					CT449	Generators and associated devices		A0705	Battery Problem	15/06/2022	15/06/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
						F1903	Device Explanation	A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
					CT981	Single use		A0705	Battery Problem	15/06/2022	15/06/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
						F1903	Device Explanation	A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
					CT983	Surgical invasive		A0705	Battery Problem	15/06/2022	15/06/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
						F1903	Device Explanation	A0705	Battery Problem	15/06/2022	15/06/2022
								A070504	Premature Discharge of Battery	15/06/2022	15/06/2022
3722	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	22/07/2022	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2022
								A070504	Premature Discharge of Battery	22/07/2022	22/07/2022

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
3724	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A070910	Undersensing	
							E0742	Respiratory Failure	A070910	Undersensing	
							E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A070910	Undersensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	
					CT1150	Defibrillators	E0601	Arrhythmia	A070910	Undersensing	
							E0742	Respiratory Failure	A070910	Undersensing	
							E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A070910	Undersensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A070910	Undersensing	
							E0742	Respiratory Failure	A070910	Undersensing	
							E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A070910	Undersensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	
					CT145	Cardiovascular devices	E0601	Arrhythmia	A070910	Undersensing	
							E0742	Respiratory Failure	A070910	Undersensing	
							E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A070910	Undersensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	
					CT233	Surgical	E0601	Arrhythmia	A070910	Undersensing	
							E0742	Respiratory Failure	A070910	Undersensing	
							E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A070910	Undersensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	
					CT2406	Implantable	E0601	Arrhythmia	A070910	Undersensing	
							E0742	Respiratory Failure	A070910	Undersensing	
							E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A070910	Undersensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	
					CT2407	Active implantable	E0601	Arrhythmia	A070910	Undersensing	
							E0742	Respiratory Failure	A070910	Undersensing	

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		F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
				A0705	Battery Problem	25/11/2021	25/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
				A0705	Battery Problem	25/11/2021	25/11/2021
CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
				A0705	Battery Problem	25/11/2021	25/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT141	Electrodes/Leads and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT233	Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
				A070504	Premature Discharge of Battery	25/11/2021	25/11/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/11/2021	25/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/11/2021	25/11/2021

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					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
3728	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
									A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
									A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
									A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
									A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
									A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
									A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
									A0705	Battery Problem	09/11/2021	09/11/2021
									A070504	Premature Discharge of Battery	09/11/2021	09/11/2021

		F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
CT258	Implantable defibrillators			A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT2727	Active implant devices/ancillaries	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT3006	Implantable inorganic material	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT314	Electrically powered	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
CT449	Generators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021

						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
								A0705	Battery Problem	09/11/2021	09/11/2021
								A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
					CT981	Single use		A0705	Battery Problem	09/11/2021	09/11/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
								A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
								A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
					CT983	Surgical invasive		A0705	Battery Problem	09/11/2021	09/11/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021	09/11/2021
								A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
								A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
3729	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A0712	Pacing Problem	
								A071202	Inaccurate Synchronization		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
					CT1150	Defibrillators	E0601	Arrhythmia	A0712	Pacing Problem	
								A071202	Inaccurate Synchronization		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
					CT1141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A0712	Pacing Problem	
								A071202	Inaccurate Synchronization		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
					CT1145	Cardiovascular devices	E0601	Arrhythmia	A0712	Pacing Problem	
								A071202	Inaccurate Synchronization		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
					CT1233	Surgical	E0601	Arrhythmia	A0712	Pacing Problem	
								A071202	Inaccurate Synchronization		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
					CT2406	Implantable	E0601	Arrhythmia	A0712	Pacing Problem	
								A071202	Inaccurate Synchronization		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
					CT2407	Active implantable	E0601	Arrhythmia	A0712	Pacing Problem	

							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT3002	implantable synthetic polymer	E0601	Arrhythmia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT3006	Implantable inorganic material	E0601	Arrhythmia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT3007	implantable ceramic	E0601	Arrhythmia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT314	Electrically powered	E0601	Arrhythmia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT321	Long-term surgical invasive	E0601	Arrhythmia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT449	Generators and associated devices	E0601	Arrhythmia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT981	Single use	E0601	Arrhythmia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT983	Surgical invasive	E0601	Arrhythmia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
3730	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
									A0705	Battery Problem	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
									A0705	Battery Problem	28/06/2022	29/06/2022
									A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/06/2022	29/06/2022
									A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
									A0705	Battery Problem	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
									A0705	Battery Problem	28/06/2022	29/06/2022
					CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/06/2022	29/06/2022
									A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/06/2022	29/06/2022
									A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/06/2022	29/06/2022
									A070504	Premature Discharge of Battery	28/06/2022	29/06/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022

				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
		F08	Hospitalization or Prolonged Hospitalization	A070502	Battery Problem	28/06/2022	28/06/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
CT2407	Active implantable			A0705	Battery Problem	28/06/2022	28/06/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A070504	Premature Discharge of Battery	28/06/2022	28/06/2022
				A0705	Battery Problem	28/06/2022	28/06/2022
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					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/06/2022	29/06/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/06/2022	29/06/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/06/2022	29/06/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	28/06/2022	29/06/2022
3731	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/06/2022	29/06/2022
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery		
									A0705	Battery Problem		
3732	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
							F1901	Additional Surgery	A0705	Premature Discharge of Battery	12/10/2021	12/10/2021
3733	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	11/07/2022	11/07/2022

						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
3734	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022
						F1908	Prolonged Surgery	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022
						F1908	Prolonged Surgery	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022
						F1908	Prolonged Surgery	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022
						F1908	Prolonged Surgery	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022
						F1908	Prolonged Surgery	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022
						F1908	Prolonged Surgery	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022
						F1908	Prolonged Surgery	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022

		F1908	Prolonged Surgery	A070101 A070909 A12	Failure to Capture Oversensing Connection Problem	26/05/2022 26/05/2022 26/05/2022	26/05/2022 26/05/2022 26/05/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
		F1908	Prolonged Surgery	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	26/05/2022	26/05/2022
				A070909	Oversensing	26/05/2022	26/05/2022
				A12	Connection Problem	26/05/2022	26/05/2022

						F1908	Prolonged Surgery	A12	Connection Problem	28/05/2022	28/05/2022
								A070101	Failure to Capture	28/05/2022	28/05/2022
								A070909	Oversensing	28/05/2022	28/05/2022
								A12	Connection Problem	28/05/2022	28/05/2022
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	28/05/2022	28/05/2022
								A070909	Oversensing	28/05/2022	28/05/2022
								A12	Connection Problem	28/05/2022	28/05/2022
						F1908	Prolonged Surgery	A070101	Failure to Capture	28/05/2022	28/05/2022
								A070909	Oversensing	28/05/2022	28/05/2022
								A12	Connection Problem	28/05/2022	28/05/2022
3735	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
				CT3114	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
								A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
						F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
							F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
							F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
									A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	31/03/2022	31/03/2022
							F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
									A070909	Oversensing	31/03/2022	31/03/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
							F13	Misdiagnosis/ Misclassification	A070909	Oversensing	31/03/2022	31/03/2022
									A090801	Signal Artifact/Noise	31/03/2022	31/03/2022
3736	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2021	14/10/2021

3737	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3738	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3739	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/10/2021	13/10/2021

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3741	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/12/2021	24/12/2021
							E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3007	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	E2104	Electric Shock	A0712	Pacing Problem		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT321	E2104	Electric Shock	A0712	Pacing Problem		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT449	E2104	Electric Shock	A0712	Pacing Problem		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT981	E2104	Electric Shock	A0712	Pacing Problem		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	E2104	Electric Shock	A0712	Pacing Problem		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
3742	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022
					CT1147	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022
					CT141	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
					CT145	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022
					CT233	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
					CT2406	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022
					CT2407	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022

CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
				A0705	Battery Problem	21/09/2022	21/09/2022
				A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
		A070504	Premature Discharge of Battery	21/09/2022	21/09/2022		
		A0705	Battery Problem	21/09/2022	21/09/2022		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery				

							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	21/09/2022	21/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
									A0705	Battery Problem	21/09/2022	21/09/2022
									A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
3743	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT12406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT12407	Active implantable	E2104	Electric Shock	A070909	Oversensing		

					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock		A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock		A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock		A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock		A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock		A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock		A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock		A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		

					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT3001	Implantable metal	E2104	Electric Shock		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT3002	Implantable synthetic polymer	E2104	Electric Shock		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT3006	Implantable inorganic material	E2104	Electric Shock		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT3007	Implantable ceramic	E2104	Electric Shock		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT314	Electrically powered	E2104	Electric Shock		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT321	Long-term surgical invasive	E2104	Electric Shock		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT449	Generators and associated devices	E2104	Electric Shock		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			

					CT1981	Single use	E2104	Electric Shock	A1301 A070909 A071302 A090801 A1301	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT1983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
3744	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		

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CT2407	Active implantable	F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		

				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
C12866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
C12985	Active	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
C13001	Implantable metal	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
C13002	Implantable synthetic polymer	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
C13006	Implantable inorganic material	E2104	Electric Shock	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

CT3007	Implantable ceramic	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT981	Single use	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT983	Surgical invasive	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070910	Undersensing		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070910 A071302 A090801 A1301	Failure to Read Input Signal Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
						F2203	Imaging Required	A070910 A071302 A090801 A1301	Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
3750	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1150	Defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1141	Electrodes/Leads and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1145	Cardiovascular devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1233	Surgical	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT12406	Implantable	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT12407	Active implantable	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1258	Implantable defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT12727	Active implant devices/ancillaries	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT12866	Implantable cardiac electrical stimulators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT12985	Active	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT13001	Implantable metal	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT13002	Implantable synthetic polymer	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT13006	Implantable inorganic material	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT13007	Implantable ceramic	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1314	Electrically powered	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1321	Long-term surgical invasive	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1449	Generators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/2022
					CT1981	Single use	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/05/2022 12/05/2022 12/05/

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				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A071302 A1301	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT145	Cardiovascular devices	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT233	Surgical	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2406	Implantable	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2407	Active implantable	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock			A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions			A070909	Oversensing		

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CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
				A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070505	Battery Problem	29/09/2022	29/09/2022
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022

		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT263	Cardiographs and associated devices	F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2726	Physiological monitoring/measuring devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2965	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT3001	Implantable metal	F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT3002	Implantable synthetic polymer	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT3007	Implantable ceramic	F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT314	Electrically powered	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT449	Generators and associated devices	F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/01/2022	25/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
									A0705	Battery Problem	25/01/2022	25/01/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
									A0705	Battery Problem	25/01/2022	25/01/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/01/2022	25/01/2022
									A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
							F1903	Device Explanation	A0705	Battery Problem	25/01/2022	25/01/2022
									A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
3758	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
CT2407	Active implantable	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		

CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A070910	Undersensing		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A070910	Undersensing		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A070910	Undersensing		
CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		

						E2403	No Clinical Signs, Symptoms or Conditions	A1301 A070909 A070910 A071302	Failure to Read Input Signal Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A070910 A071302	Failure to Read Input Signal Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
				CT981	Single use	E2104	Electric Shock	A1301 A070909 A070910 A071302	Failure to Read Input Signal Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A1301 A070909 A070910 A071302	Failure to Read Input Signal Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A070910 A071302	Failure to Read Input Signal Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
				CT983	Surgical invasive	E2104	Electric Shock	A1301 A070909 A070910 A071302	Failure to Read Input Signal Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A1301 A070909 A070910 A071302	Failure to Read Input Signal Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A070910 A071302	Failure to Read Input Signal Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
3759	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	

3760	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT233	Surgical	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2406	Implantable	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2407	Active implantable	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2985	Active	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3001	Implantable metal	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3007	Implantable ceramic	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT314	Electrically powered	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT449	Generators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT981	Single use	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	Surgical invasive	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
3761	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2021	04/11/2021
					CT1147	Defibrillators and associated devices			A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/11/2021	04/11/2021

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					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	04/11/2021	04/11/2021
									A070504	Battery Problem	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	04/11/2021	04/11/2021
									A070504	Battery Problem	04/11/2021	04/11/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
									A0705	Battery Problem	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
									A0705	Battery Problem	04/11/2021	04/11/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
									A0705	Battery Problem	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
									A0705	Battery Problem	04/11/2021	04/11/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
									A0705	Battery Problem	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
									A0705	Battery Problem	04/11/2021	04/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2021	04/11/2021
									A070504	Premature Discharge of Battery	04/11/2021	04/11/2021
3762	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					C12750	Implantable cardiac electrical stimulators and associated devices	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT2866	Implantable cardiac electrical stimulators	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT2985	Active	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT3001	Implantable metal	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT3002	Implantable synthetic polymer	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT3006	Implantable inorganic material	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT3007	Implantable ceramic	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT314	Electrically powered	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT321	Long-term surgical invasive	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT449	Generators and associated devices	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT981	Single use	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
					CT983	Surgical invasive	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	
3763	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Battery Problem Premature Discharge of Battery Battery Problem Premature Discharge of Battery	16/12/2021 16/12/2021 16/12/2021 16/12/2021
					CT1147	Defibrillators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Battery Problem Premature Discharge of Battery Battery Problem Premature Discharge of Battery	16/12/2021 16/12/2021 16/12/2021 16/12/2021
					CT1150	Defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Battery Problem Premature Discharge of Battery Battery Problem Premature Discharge of Battery	16/12/2021 16/12/2021 16/12/2021 16/12/2021
					CT141	Electrodes/Leads and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Battery Problem Premature Discharge of Battery Battery Problem Premature Discharge of Battery	16/12/2021 16/12/2021 16/12/2021 16/12/2021
					CT145	Cardiovascular devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Battery Problem Premature Discharge of Battery Battery Problem Premature Discharge of Battery	16/12/2021 16/12/2021 16/12/2021 16/12/2021
					CT233	Surgical	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Battery Problem Premature Discharge of Battery Battery Problem Premature Discharge of Battery	16/12/2021 16/12/2021 16/12/2021 16/12/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	16/12/2021 16/12/2021

CT2407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
				A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT3008	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021
				A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/12/2021	16/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021

								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
								F1905	Device Revision or Replacement	A0705	Battery Problem	16/12/2021	16/12/2021
										A070504	Premature Discharge of Battery	16/12/2021	16/12/2021
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021	
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/12/2021	16/12/2021	
									A070504	Premature Discharge of Battery	16/12/2021	16/12/2021	
					C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/12/2021	16/12/2021	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/12/2021	16/12/2021	
							F1905	Device Revision or Replacement	A0705	Battery Problem	16/12/2021	16/12/2021	
									A070504	Premature Discharge of Battery	16/12/2021	16/12/2021	
3764	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/07/2022	12/07/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/07/2022	12/07/2022	
									A070504	Premature Discharge of Battery	12/07/2022	12/07/2022	

CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT2727	Active implant devices/ancillaries	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT2985	Active	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021
				A070504	Premature Discharge of Battery	09/11/2021	09/11/2021
				A0705	Battery Problem	09/11/2021	09/11/2021

						F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021	09/11/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2021
									A070504	Premature Discharge of Battery	09/11/2021
3766	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
3767	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712		
3768	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021
									A0705	Battery Problem	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021
									A0705	Battery Problem	19/11/2021
									A070504	Premature Discharge of Battery	19/11/2021

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					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/11/2021	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/11/2021	19/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	19/11/2021	19/11/2021
3769	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021

		F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
				A0705	Battery Problem	10/11/2021	10/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
				A0705	Battery Problem	10/11/2021	10/11/2021
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
				A0705	Battery Problem	10/11/2021	10/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT3007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
CT449	Generators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
				A070504	Premature Discharge of Battery	10/11/2021	10/11/2021

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A0705	Battery Problem	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A0705	Battery Problem	10/11/2021	10/11/2021
									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
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									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
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									A070504	Premature Discharge of Battery	10/11/2021	10/11/2021
									A0705	Battery Problem	10/11/2021	10/11/2021
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CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	25/10/2021	26/10/2021
				A0203	Defective Device	25/10/2021	26/10/2021
				A070101	Failure to Capture	25/10/2021	26/10/2021
				A0709	Device Sensing Problem	25/10/2021	26/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
		F1901	Additional Surgery	A072201	High Impedance	25/10/2021	25/10/2021
				A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	25/10/2021	25/10/2021
				A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
		F1901	Additional Surgery	A072201	High Impedance	25/10/2021	25/10/2021
				A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	25/10/2021	25/10/2021
				A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
		F1901	Additional Surgery	A072201	High Impedance	25/10/2021	25/10/2021
				A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021

				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
C1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021
				A0709	Device Sensing Problem	25/10/2021	25/10/2021
				A070909	Oversensing	25/10/2021	25/10/2021
				A072201	High Impedance	25/10/2021	25/10/2021
		F1901	Additional Surgery	A0203	Defective Device	25/10/2021	25/10/2021
				A070101	Failure to Capture	25/10/2021	25/10/2021

									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
									A072201	High Impedance	25/10/2021	25/10/2021
				Ct321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
						F1901	Additional Surgery		A072201	High Impedance	25/10/2021	25/10/2021
									A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
									A072201	High Impedance	25/10/2021	25/10/2021
									A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
									A072201	High Impedance	25/10/2021	25/10/2021
				Ct449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
						F1901	Additional Surgery		A072201	High Impedance	25/10/2021	25/10/2021
									A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
									A072201	High Impedance	25/10/2021	25/10/2021
									A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
									A072201	High Impedance	25/10/2021	25/10/2021
				Ct981	Single use	E2403	No Clinical Signs, Symptoms or Conditions		A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
						F1901	Additional Surgery		A072201	High Impedance	25/10/2021	25/10/2021
									A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
									A072201	High Impedance	25/10/2021	25/10/2021
				Ct983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
						F1901	Additional Surgery		A072201	High Impedance	25/10/2021	25/10/2021
									A0203	Defective Device	25/10/2021	25/10/2021
									A070101	Failure to Capture	25/10/2021	25/10/2021
									A0709	Device Sensing Problem	25/10/2021	25/10/2021
									A070909	Oversensing	25/10/2021	25/10/2021
									A072201	High Impedance	25/10/2021	25/10/2021
3772	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	Ct1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
					Ct1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
					Ct1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
					Ct141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
					Ct145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
					Ct233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
					Ct2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
					Ct2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	01/12/2021	01/12/2021
									A070504	Premature Discharge of Battery	01/12/2021	01/12/2021

		F1905	Device Revision or Replacement	A0705	Battery Problem	01/12/2021	01/12/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT2726	Physiological monitoring/measuring devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT3002	Implantable synthetic polymer	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT314	Electrically powered	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021
CT981	Single use	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2021	01/12/2021
				A0705	Battery Problem	01/12/2021	01/12/2021

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					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3775	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		

						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
										A160601	Premature Elective Replacement Indicator			
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
										A070504	Premature Discharge of Battery			
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
										A160601	Premature Elective Replacement Indicator			
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
										A160601	Premature Elective Replacement Indicator			
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
										A070504	Premature Discharge of Battery			
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
										A160601	Premature Elective Replacement Indicator			
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
										A160601	Premature Elective Replacement Indicator			
3776	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			
										A070102	High Capture Threshold			
										A070909	Oversensing			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold				
								F26	No Health Consequences or Impact	A070909	Oversensing			

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070102	High Capture Threshold		
									A070909	Oversensing		
									A070102	High Capture Threshold		
									A070909	Oversensing		
3/77	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070409	Battery Problem	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/08/2022	04/08/2022

		F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
				A0705	Battery Problem	24/11/2021	24/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
				A0705	Battery Problem	24/11/2021	24/11/2021
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
				A0705	Battery Problem	24/11/2021	24/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT2407	Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT3001	Implantable metal	F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT3002	Implantable synthetic polymer	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
CT314	Electrically powered	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2021	24/11/2021
				A070504	Premature Discharge of Battery	24/11/2021	24/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2021	24/11/2021

							F1905	Device Revision or Replacement	A070504 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021 24/11/2021	24/11/2021 24/11/2021 24/11/2021
				CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
				CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
				CT981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
				CT983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	24/11/2021 24/11/2021	24/11/2021 24/11/2021
3779	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping device	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0508 A070504	Premature Discharge of Battery Noise, Audible Premature Discharge of Battery	24/11/2021	24/11/2021
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0508 A070504	Premature Discharge of Battery Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A070504	Noise, Audible Premature Discharge of Battery		
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0508	Premature Discharge of Battery Noise, Audible		

						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/10/2021	27/10/2021	
						F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/10/2021	27/10/2021	
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/10/2021	27/10/2021	
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/10/2021	27/10/2021	
						F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/10/2021	27/10/2021	
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/10/2021	27/10/2021	
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/10/2021	27/10/2021	
						F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/10/2021	27/10/2021	
3781	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT123	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT3006	implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/06/2022	17/06/2022
3782	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
				CT123	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022	
							A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	

				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A070505	Battery Problem	06/10/2022	06/10/2022
						A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
					A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
					A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022
						A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
CT2726	Physiological monitoring/measuring devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
					A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022
						A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022
						A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022
				F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
						A0705	Battery Problem	06/10/2022	06/10/2022
CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022	06/10/2022
					A0705	Battery Problem	06/10/2022	06/10/2022	06/10/2022

							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
									A0705	Battery Problem	06/10/2022	06/10/2022
									A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022
									A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022
									A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022
									A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/10/2022	06/10/2022
									A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/10/2022	06/10/2022
									A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	06/10/2022	06/10/2022
									A070504	Premature Discharge of Battery	06/10/2022	06/10/2022
3783	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/10/2021	22/10/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	22/10/2021	22/10/2021
3784	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909 A071302 A1301	Oversensing Inappropriate/inadequate Shock/Stimulation Failure to Read Input Signal		
3785	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090805	Premature Discharge of Battery Incorrect Measurement	01/11/2021 01/11/2021	01/11/2021 01/11/2021
							F1901	Additional Surgery	A070504 A090805	Premature Discharge of Battery Incorrect Measurement	01/11/2021 01/11/2021	01/11/2021 01/11/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090805	Premature Discharge of Battery Incorrect Measurement	01/11/2021 01/11/2021	01/11/2021 01/11/2021
							F1901	Additional Surgery	A070504 A090805	Premature Discharge of Battery Incorrect Measurement	01/11/2021 01/11/2021	01/11/2021 01/11/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090805	Premature Discharge of Battery Incorrect Measurement	01/11/2021 01/11/2021	01/11/2021 01/11/2021
							F1901	Additional Surgery	A070504 A090805	Premature Discharge of Battery Incorrect Measurement	01/11/2021 01/11/2021	01/11/2021 01/11/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090805	Premature Discharge of Battery Incorrect Measurement	01/11/2021 01/11/2021	01/11/2021 01/11/2021
							F1901	Additional Surgery	A070504 A090805	Premature Discharge of Battery Incorrect Measurement	01/11/2021 01/11/2021	01/11/2021 01/11/2021

					CT1233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT12408	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT12407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT1258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT12727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT12750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT12866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT12985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT13001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT13002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT13008	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT13007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT1314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT1321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT1449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT1981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
					CT1983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2021	01/11/2021
							F1901	Additional Surgery	A070504	Incorrect Measurement	01/11/2021	01/11/2021	
3786	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/06/2022	26/06/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/06/2022	26/06/2022	
							F1903	Device Explanation	A0705	Battery Problem	26/06/2022	26/06/2022	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/06/2022	26/06/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/06/2022	26/06/2022	
							F1903	Device Explanation	A0705	Battery Problem	26/06/2022	26/06/2022	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/06/2022	26/06/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/06/2022	26/06/2022	
							F1903	Device Explanation	A0705	Battery Problem	26/06/2022	26/06/2022	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/06/2022	26/06/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/06/2022	26/06/2022	

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						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
3788	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/08/2022	08/08/2022
								A070504	Premature Discharge of Battery	08/08/2022	08/08/2022

						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2022	08/08/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
										A0705	Battery Problem	08/08/2022	08/08/2022
										A070504	Premature Discharge of Battery	08/08/2022	08/08/2022
3789	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/01/2022	25/01/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/01/2022	25/01/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
										A0705	Battery Problem	25/01/2022	25/01/2022
										A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/01/2022	25/01/2022	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
										A0705	Battery Problem	25/01/2022	25/01/2022

CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
				A0705	Battery Problem	25/01/2022	25/01/2022

						F1905	Device Revision or Replacement	A0705	Battery Problem	25/01/2022	25/01/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022
								A0705	Battery Problem	25/01/2022	25/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
								A0705	Battery Problem	25/01/2022	25/01/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/01/2022
								A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/01/2022	25/01/2022
								A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	25/01/2022	25/01/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022
								A0705	Battery Problem	25/01/2022	25/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
								A0705	Battery Problem	25/01/2022	25/01/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/01/2022
								A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/01/2022	25/01/2022
								A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	25/01/2022	25/01/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2022
								A0705	Battery Problem	25/01/2022	25/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
								A0705	Battery Problem	25/01/2022	25/01/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/01/2022
								A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/01/2022	25/01/2022
								A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	25/01/2022	25/01/2022
								A070504	Premature Discharge of Battery	25/01/2022	25/01/2022
3790	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2407	Active Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2409	Active Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		

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						E180304	Skull Fracture	A0713	Defibrillation/Stimulation Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem			
						F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem			
						F1203	Life Threatening Illness or Injury	A0713	Defibrillation/Stimulation Problem			
						F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem			
					C1983	E080110	Ventricular Fibrillation	A0713	Defibrillation/Stimulation Problem			
						E180304	Skull Fracture	A0713	Defibrillation/Stimulation Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem			
						F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem			
						F1203	Life Threatening Illness or Injury	A0713	Defibrillation/Stimulation Problem			
						F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem			
3795	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	C11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
					C11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
					C11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
					C1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021	
								A070504	Premature Discharge of Battery		08/11/2021	08/11/202

		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
CT2727	Active implant devices/ancillaries			A0705	Battery Problem	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
CT2985	Active			A0705	Battery Problem	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
CT3006	Implantable inorganic material			A0705	Battery Problem	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
CT3007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
				A0705	Battery Problem	08/11/2021	08/11/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
CT321	Long-term surgical invasive			A0705	Battery Problem	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/11/2021	08/11/2021
				A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021

					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2021	08/11/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	08/11/2021	08/11/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2021	08/11/2021
3796	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1001	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
3797	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2022	29/09/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2022	29/09/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2022	29/09/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2022	29/09/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/09/2022	29/09/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022

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3801	2021	All other reportable incidents	35852		CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
					F26	No Health Consequences or Impact	A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
					F26	No Health Consequences or Impact	A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							A0705	Battery Problem									
							A070504	Premature Discharge of Battery									
					3801	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		A0705	Battery Problem	07/12/2021								07/12/2021					
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2021								07/12/2021					
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705						Battery Problem	07/12/2021	07/12/2021					
		F08	Hospitalization or Prolonged Hospitalization	A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
				A0705						Battery Problem	07/12/2021	07/12/2021					
		F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705						Battery Problem	07/12/2021	07/12/2021					
		F08	Hospitalization or Prolonged Hospitalization	A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
				A0705						Battery Problem	07/12/2021	07/12/2021					
		F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705						Battery Problem	07/12/2021	07/12/2021					
				A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
		F1905	Device Revision or Replacement	A0705						Battery Problem	07/12/2021	07/12/2021					
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705						Battery Problem	07/12/2021	07/12/2021					
				A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
		F1905	Device Revision or Replacement	A0705						Battery Problem	07/12/2021	07/12/2021					
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
		F08	Hospitalization or Prolonged Hospitalization	A0705						Battery Problem	07/12/2021	07/12/2021					
				A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
		F1905	Device Revision or Replacement	A0705						Battery Problem	07/12/2021	07/12/2021					
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
				A0705						Battery Problem	07/12/2021	07/12/2021					
				A070504						Premature Discharge of Battery	07/12/2021	07/12/2021					
				A0705						Battery Problem	07/12/2021	07/12/2021					

				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070505	Battery Problem	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT2407	Active implantable			A0705	Battery Problem	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
				A0705	Battery Problem	07/12/2021	07/12/2021
CT258	Implantable defibrillators			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A070505	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT263	Cardiographs and associated devices			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT12726	Physiological monitoring/measuring devices			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT12727	Active implant devices/ancillaries			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
				A0705	Battery Problem	07/12/2021	07/12/2021
CT12750	Implantable cardiac electrical stimulators and associated devices			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT12866	Implantable cardiac electrical stimulators			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT12985	Active			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT13001	Implantable metal			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
				A0705	Battery Problem	07/12/2021	07/12/2021
CT13002	Implantable synthetic polymer			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT13006	Implantable inorganic material			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT13007	Implantable ceramic			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
CT1314	Electrically powered			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
				A0705	Battery Problem	07/12/2021	07/12/2021
CT1321	Long-term surgical invasive			A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/12/2021	07/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2021	07/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	07/12/2021	07/12/2021
				A070504	Premature Discharge of Battery	07/12/2021	07/12/2021

				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F2203	Imaging Required	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F2203	Imaging Required	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
CT1150	Defibrillators	E2104	Electric Shock	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F2203	Imaging Required	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F2203	Imaging Required	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
CT1145	Cardiovascular devices	E2104	Electric Shock	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F1903	Device Explanation	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F2203	Imaging Required	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
CT1233	Surgical	E2104	Electric Shock	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2022	25/11/2022

CT2406	implantable	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
		F1903	Device Explanation	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
	F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022		
			A090801	Signal Artifact/Noise	25/11/2022	25/11/2022		
			A070504	Premature Discharge of Battery	25/11/2022	25/11/2022		
	CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
					A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
					A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
			E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
					A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
					A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
			F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022
					A090801	Signal Artifact/Noise	25/11/2022	25/11/2022
					A070504	Premature Discharge of Battery	25/11/2022	25/11/2022
F10			Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
				A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
F1903	Device Explanation	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022			
		A090801	Signal Artifact/Noise	25/11/2022	25/11/2022			
		A070504	Premature Discharge of Battery	25/11/2022	25/11/2022			
F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022			
		A090801	Signal Artifact/Noise	25/11/2022	25/11/2022			
		A070504	Premature Discharge of Battery	25/11/2022	25/11/2022			
CT258	implantable defibrillators	E2104	Electric Shock	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		F1903	Device Explanation	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		F2203	Imaging Required	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
CT263	Cardiographs and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		F1903	Device Explanation	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		F2203	Imaging Required	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	25/11/2022	25/11/2022	
				A070504	Premature Discharge of Battery	25/11/2022	25/11/2022	
				A071302	Inappropriate/Inadequate Shock/Stimulation	25/11/2022	25/11/2022	

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CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT233	Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT12727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT12750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT12985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
				A070504	Premature Discharge of Battery	06/12/2021	06/12/2021

						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
										A0705	Battery Problem	06/12/2021	06/12/2021
						F08	Hospitalization or Prolonged Hospitalization			A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
										A0705	Battery Problem	06/12/2021	06/12/2021
						F1905	Device Revision or Replacement			A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
										A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F1905	Device Revision or Replacement			A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
										A0705	Battery Problem	06/12/2021	06/12/2021
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	06/12/2021	06/12/2021
										A070504	Premature Discharge of Battery	06/12/2021	06/12/2021
3008	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F08	Hospitalization or Prolonged Hospitalization		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F1905	Device Revision or Replacement		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F1908	Prolonged Surgery		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F08	Hospitalization or Prolonged Hospitalization		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F1905	Device Revision or Replacement		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F1908	Prolonged Surgery		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F08	Hospitalization or Prolonged Hospitalization		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F1905	Device Revision or Replacement		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						F1908	Prolonged Surgery		A04	Material Integrity Problem	26/11/2021	26/11/2021	
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	
						CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021
									A070504	Premature Discharge of Battery	26/11/2021	26/11/2021	
									A12	Connection Problem	26/11/2021	26/11/2021	
									A150207	Difficult to Remove	26/11/2021	26/11/2021	

		F08	Hospitalization or Prolonged Hospitalization	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1905	Device Revision or Replacement	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1905	Device Revision or Replacement	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1905	Device Revision or Replacement	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26

				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				A12	Connection Problem	26/11/2021	26/11/2021		
				A150207	Difficult to Remove	26/11/2021	26/11/2021		
C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				A12	Connection Problem	26/11/2021	26/11/2021		
				F08	Hospitalization or Prolonged Hospitalization	A150207	Difficult to Remove	26/11/2021	26/11/2021
		A04	Material Integrity Problem			26/11/2021	26/11/2021		
		A070504	Premature Discharge of Battery			26/11/2021	26/11/2021		
						A12	Connection Problem	26/11/2021	26/11/2021
						A150207	Difficult to Remove	26/11/2021	26/11/2021
				F1905	Device Revision or Replacement	A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
						A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				A12	Connection Problem	26/11/2021	26/11/2021		
C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A150207	Difficult to Remove	26/11/2021	26/11/2021		
				A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				F08	Hospitalization or Prolonged Hospitalization	A12	Connection Problem	26/11/2021	26/11/2021
						A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
				F1905	Device Revision or Replacement	A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021		
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				A12	Connection Problem	26/11/2021	26/11/2021		
C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A150207	Difficult to Remove	26/11/2021	26/11/2021		
				A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				F08	Hospitalization or Prolonged Hospitalization	A12	Connection Problem	26/11/2021	26/11/2021
						A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
				F1905	Device Revision or Replacement	A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021		
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				A12	Connection Problem	26/11/2021	26/11/2021		
C13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A150207	Difficult to Remove	26/11/2021	26/11/2021		
				A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				F08	Hospitalization or Prolonged Hospitalization	A12	Connection Problem	26/11/2021	26/11/2021
						A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
				F1905	Device Revision or Replacement	A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021		
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				A12	Connection Problem	26/11/2021	26/11/2021		
C13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A150207	Difficult to Remove	26/11/2021	26/11/2021		
				A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				F08	Hospitalization or Prolonged Hospitalization	A12	Connection Problem	26/11/2021	26/11/2021
						A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
				F1905	Device Revision or Replacement	A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
						A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021		
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				A12	Connection Problem	26/11/2021	26/11/2021		
C13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A150207	Difficult to Remove	26/11/2021	26/11/2021		
				A04	Material Integrity Problem	26/11/2021	26/11/2021		
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
				F08	Hospitalization or Prolonged Hospitalization	A12	Connection Problem	26/11/2021	26/11/2021
						A150207	Difficult to Remove	26/11/2021	26/11/2021
						A04	Material Integrity Problem	26/11/2021	26/11/2021
						A070504	Premature Discharge of Battery	26/11/2021	26/11/2021

				A150207	Difficult to Remove	26/11/2021	26/11/2021
				A04	Material Integrity Problem	26/11/2021	26/11/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1905	Device Revision or Replacement	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1905	Device Revision or Replacement	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F08	Hospitalization or Prolonged Hospitalization	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1905	Device Revision or Replacement	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021
				A150207	Difficult to Remove	26/11/2021	26/11/2021
		F1908	Prolonged Surgery	A04	Material Integrity Problem	26/11/2021	26/11/2021
				A070504	Premature Discharge of Battery	26/11/2021	26/11/2021
				A12	Connection Problem	26/11/2021	26/11/2021

					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A150207 A04 A070504 A12 A150207	Difficult to Remove Material Integrity Problem Premature Discharge of Battery Connection Problem Difficult to Remove	28/11/2021 28/11/2021 28/11/2021 28/11/2021 28/11/2021	28/11/2021 28/11/2021 28/11/2021 28/11/2021 28/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A04 A070504 A12 A150207	Material Integrity Problem Premature Discharge of Battery Connection Problem Difficult to Remove	28/11/2021 28/11/2021 28/11/2021 28/11/2021	28/11/2021 28/11/2021 28/11/2021 28/11/2021
							F1905	Device Revision or Replacement	A04 A070504 A12 A150207	Material Integrity Problem Premature Discharge of Battery Connection Problem Difficult to Remove	28/11/2021 28/11/2021 28/11/2021 28/11/2021	28/11/2021 28/11/2021 28/11/2021 28/11/2021
							F1908	Prolonged Surgery	A04 A070504 A12 A150207	Material Integrity Problem Premature Discharge of Battery Connection Problem Difficult to Remove	28/11/2021 28/11/2021 28/11/2021 28/11/2021	28/11/2021 28/11/2021 28/11/2021 28/11/2021
3807	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		

					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
3808	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

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3810	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/10/2021	14/10/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					F1905	Device Revision or Replacement	A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A070504	Battery Problem	26/11/2021	26/11/2021		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							A0705	Battery Problem	26/11/2021	26/11/2021		
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/11/2021	26/11/2021
							A070504	Premature Discharge of Battery	26/11/2021	26/11/2021		
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/11/2021	26/11/2021

										F1905	Device Revision or Replacement	A070504 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021 26/11/2021	26/11/2021 26/11/2021 26/11/2021
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021	26/11/2021 26/11/2021
3811	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	A070504	High Impedance	20/06/2022	20/06/2022		
								F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	20/06/2022	20/06/2022		
								F1905	Device Revision or Replacement	A072201	High Impedance	20/06/2022	20/06/2022		
3812	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		
								F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	04/07/2022	04/07/2022		

CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/07/2022	04/07/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/07/2022	04/07/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/07/2022	04/07/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/07/2022	04/07/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/07/2022	04/07/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/07/2022	04/07/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/07/2022	04/07/2022
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2022	04/07/2022
				A0705	Battery Problem	04/07/2022	04/07/2022
				A070504	Premature Discharge of Battery	04/07/2022	04/07/2022

CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT3007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022
				A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
				A0705	Battery Problem	12/01/2022	12/01/2022

						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022
								A070504	Premature Discharge of Battery	12/01/2022	12/01/2022

					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
3817	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2021	15/11/2021
3818	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Premature Discharge of Battery	02/11/2021	02/11/2021
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/11/2021	02/11/2021
									A070602	Delayed Charge Time	02/11/2021	02/11/2021
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/11/2021	02/11/2021
									A070602	Delayed Charge Time	02/11/2021	02/11/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Premature Discharge of Battery	02/11/2021	02/11/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/11/2021	02/11/2021

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CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

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						F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2021	30/11/2021
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
								A0705	Battery Problem	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2021	30/11/2021
								A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
						F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	30/11/2021	30/11/2021
								A070504	Battery Problem	30/11/2021	30/11/2021
3821	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

					CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	implantable metal	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	implantable synthetic polymer	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1981	Single use	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
3822	2021	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem	2011/2021	2011/2021
							E060110	Ventricular Fibrillation	A0709	Device Sensing Problem	2011/2021	2011/2021
							E0602	Cardiac Arrest	A0709	Device Sensing Problem	2011/2021	2011/2021
							F02	Death	A0709	Device Sensing Problem	2011/2021	2011/2021
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	2011/2021	2011/2021
							F2306	Resuscitation	A0709	Device Sensing Problem	2011/2021	2011/2021
3823	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F24	Insufficient Health Impact Information	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F24	Insufficient Health Impact Information	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem		
					CT141	Electrodes/Leads end associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Battery Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Battery Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Battery Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F24	Insufficient Health Impact Information	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
					CT2750	implantable cardiac electrical stimulators and associated devices	F24	Insufficient Health Impact Information	A070504	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F24	Insufficient Health Impact Information	A070504	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
					CT2985	Active	F24	Insufficient Health Impact Information	A070504	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Battery Problem		
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Battery Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Battery Problem		

		F08		Hospitalization or Prolonged Hospitalization	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F1905		Device Revision or Replacement	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		CT1147	Defibrillators and associated devices	E2104	Electric Shock	A010402	Migration			
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration					
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F08		Hospitalization or Prolonged Hospitalization	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F1905		Device Revision or Replacement	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		E2104	Electric Shock	A010402	Migration					
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration					
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F08		Hospitalization or Prolonged Hospitalization	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F1905		Device Revision or Replacement	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A010402	Migration			
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration					
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F08		Hospitalization or Prolonged Hospitalization	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F1905		Device Revision or Replacement	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		CT145	Cardiovascular devices	E2104	Electric Shock	A010402	Migration			
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration					
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F08		Hospitalization or Prolonged Hospitalization	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F1905		Device Revision or Replacement	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		CT233	Surgical	E2104	Electric Shock	A010402	Migration			
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration					
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F08		Hospitalization or Prolonged Hospitalization	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		F1905		Device Revision or Replacement	A010402	Migration				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		CT2406	Implantable	E2104	Electric Shock	A010402	Migration			
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration					
					A071302	Inappropriate/Inadequate Shock/Stimulation				
					A072201	High Impedance				

		F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
				A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT2407	Active implantable	E2104	Electric Shock	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT258	Implantable defibrillators	E2104	Electric Shock	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A010402	Migration		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		

				F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
						A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				F1905	Device Revision or Replacement	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				CT2966	Implantable cardiac electrical stimulators	E2104	Electric Shock	A010402	Migration
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A072201	High Impedance						
E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A072201	High Impedance						
F08	Hospitalization or Prolonged Hospitalization	A010402	Migration						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A072201	High Impedance						
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A072201	High Impedance						
		F1905	Device Revision or Replacement	A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		CT2985	Active	E2104	Electric Shock	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		F1905	Device Revision or Replacement	A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		CT3001	Implantable metal	E2104	Electric Shock	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		F1905	Device Revision or Replacement	A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		CT3002	Implantable synthetic polymer	E2104	Electric Shock	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		F1905	Device Revision or Replacement	A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		CT3006	Implantable inorganic material	E2104	Electric Shock	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
				F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		F1905	Device Revision or Replacement	A010402	Migration				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
		CT3007	Implantable ceramic	E2104	Electric Shock	A010402	Migration		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A072201	High Impedance		

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					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0709	Device Sensing Problem		
									A1107	Data Problem		
3828	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/10/2021	08/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/10/2021	08/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/10/2021	08/10/2021
3829	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2022	07/07/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	07/07/2022	07/07/2022
3830	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/01/2022	13/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
							F1903	Device Explanation	A070504	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/01/2022	13/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
							F1903	Device Explanation	A070504	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/01/2022	13/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
							F1903	Device Explanation	A070504	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/01/2022	13/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
							F1903	Device Explanation	A070504	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022

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					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
									A0705	Battery Problem	13/01/2022	13/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
									A0705	Battery Problem	13/01/2022	13/01/2022
						F1903	Device Explanation		A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
									A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
						F1903	Device Explanation		A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
						F1903	Device Explanation		A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
						F1903	Device Explanation		A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
						F1903	Device Explanation		A0705	Battery Problem	13/01/2022	13/01/2022
									A070504	Premature Discharge of Battery	13/01/2022	13/01/2022
3831	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A070909	Oversensing	26/11/2021	26/11/2021
									A0712	Pacing Problem	26/11/2021	26/11/2021
									A071204	No Pacing	26/11/2021	26/11/2021
									A070909	Oversensing	26/11/2021	26/11/2021
						E2403	No Clinical Signs, Symptoms or Conditions		A0712	Pacing Problem	26/11/2021	26/11/2021
									A071204	No Pacing	26/11/2021	26/11/2021
									A070909	Oversensing	26/11/2021	26/11/2021
						F26	No Health Consequences or Impact		A0712	Pacing Problem	26/11/2021	26/11/2021
									A071204	No Pacing	26/11/2021	26/11/2021
3832	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
									A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
									A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	13/07/2022	13/07/2022

				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
CT12868	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2022	13/07/2022
				A070504	Premature Discharge of Battery	13/07/2022	13/07/2022
				A1304	Telemetry Discrepancy	13/07/2022	13/07/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/07/2022	13/07/2022

		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		

3835	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
									A0705	Battery Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A1107	Data Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	02/12/2021	02/12/2021
									A1107	Data Problem	02/12/2021	02/12/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	02/12/2021	02/12/2021
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	02/12/2021	02/12/2021
							F1905	Device Revision or Replacement	A1107	Data Problem	02/12/2021	02/12/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/12/2021	02/12/2021

		F08	Hospitalization or Prolonged Hospitalization	A070504 A070504	Premature Discharge of Battery Battery Problem	08/09/2022 08/09/2022	08/09/2022 08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/09/2022	08/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	08/09/2022	08/09/2022

			L-exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A071302	Inappropriate/inadequate Shock/Stimulation		

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								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
								F1903	Device Explanation	A0705	Battery Problem	08/09/2022	08/09/2022
										A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/09/2022	08/09/2022	08/09/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
								F1903	Device Explanation	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/09/2022	08/09/2022	08/09/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
								F1903	Device Explanation	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/09/2022	08/09/2022	08/09/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A070504	Battery Problem	08/09/2022	08/09/2022
								F1903	Device Explanation	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/09/2022	08/09/2022	08/09/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
								F1903	Device Explanation	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
					CT081	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/09/2022	08/09/2022	08/09/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
								F1903	Device Explanation	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
					CT083	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/09/2022	08/09/2022	08/09/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
								F1903	Device Explanation	A070504	Premature Discharge of Battery	08/09/2022	08/09/2022
										A0705	Battery Problem	08/09/2022	08/09/2022
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022	04/08/2022
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
3844	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022	04/08/2022
3845	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			

3846	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1147	Defibrillators and associated devices		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1150	Defibrillators		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT141	Electrodes/Leads and associated devices		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT145	Cardiovascular devices		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT233	Surgical		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2406	Implantable		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2407	Active implantable		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT258	Implantable defibrillators		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT263	Cardiographs and associated devices		E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	

					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT2727	Active implant devices/ancillaries	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT2985	Active	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT3001	Implantable metal	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT3002	Implantable synthetic polymer	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT3006	Implantable inorganic material	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT3007	Implantable ceramic	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT314	Electrically powered	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			

								E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
				CT321	Long-term surgical invasive			E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
				CT449	Generators and associated devices			E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
				CT981	Single use			E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
				CT983	Surgical invasive			E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
3847	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT2726	Physiological monitoring/measuring devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
								F06	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/12/2021	08/12/2021
3548	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
									A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/08/2022	25/08/2022
									A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2022	25/08/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
									A0705	Battery Problem	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2022	25/08/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2022	25/08/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/08/2022	25/08/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
									A0705	Battery Problem	25/08/2022	25/08/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
									A0705	Battery Problem	25/08/2022	25/08/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
									A0705	Battery Problem	25/08/2022	25/08/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
									A0705	Battery Problem	25/08/2022	25/08/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
									A0705	Battery Problem	25/08/2022	25/08/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
									A070504	Premature Discharge of Battery	25/08/2022	25/08/2022

CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
				A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	02/02/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
				A0705	Battery Problem	02/02/2022	0

						F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/02/2022
								A0705	Battery Problem	02/02/2022	02/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/02/2022
								A0705	Battery Problem	02/02/2022	02/02/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/02/2022
								A0705	Battery Problem	02/02/2022	02/02/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
3854	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F1905	Device Revision or Replacement	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F1905	Device Revision or Replacement	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F1905	Device Revision or Replacement	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F1905	Device Revision or Replacement	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F1905	Device Revision or Replacement	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F1905	Device Revision or Replacement	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F1905	Device Revision or Replacement	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F1905	Device Revision or Replacement	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
								A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	

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						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
				CT149	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
						F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improper Result or Readings	01/12/2021	01/12/2021
3859	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery	
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	F15	Recognized Device or Procedural Complication	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
3863	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3864	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

					CT145	Cardiovascular devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3865	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
							F1903	Device Explanation	A070504	Battery Problem	13/10/2022	13/10/2022
									A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
					CT11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
							F1903	Device Explanation	A070504	Battery Problem	13/10/2022	13/10/2022
									A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
					CT11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
							F1903	Device Explanation	A070504	Battery Problem	13/10/2022	13/10/2022
									A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
							F1903	Device Explanation	A070504	Battery Problem	13/10/2022	13/10/2022
									A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
							F1903	Device Explanation	A070504	Battery Problem	13/10/2022	13/10/2022
									A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
							F1903	Device Explanation	A070504	Battery Problem	13/10/2022	13/10/2022
									A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
							F1903	Device Explanation	A070504	Battery Problem	13/10/2022	13/10/2022
									A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
							F1903	Device Explanation	A070504	Battery Problem	13/10/2022	13/10/2022
									A070504	Premature Discharge of Battery	13/10/2022	13/10/2022

CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			
		A070504	Premature Discharge of Battery	13/10/2022	13/10/2022			
	CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/10/2022	13/10/2022
					A070504	Premature Discharge of Battery	13/10/2022	13/10/2022
F08			Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/10/2022	13/10/2022	
				A070504	Premature Discharge of Battery	13/10/2022	13/10/2022	
F1903	Device Explanation	A0705	Battery Problem	13/10/2022	13/10/2022			

					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	13/10/2022 13/10/2022 13/10/2022	13/10/2022 13/10/2022 13/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	13/10/2022 13/10/2022	13/10/2022 13/10/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	13/10/2022 13/10/2022	13/10/2022 13/10/2022
3866	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
							F1903	Device Explanation	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/2022 15/11/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	15/11/2022 15/11/2022	15/11/

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						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2022	25/08/2022
3669	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/08/2022	30/08/2022
3670	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Overheating	30/08/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		

3671	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2311	Discomfort	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071204	No Pacing			
							F23	Unexpected Medical Intervention	A070909	Oversensing			
									A071204	No Pacing			
									A070909	Oversensing			
									A071204	No Pacing			
3872	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
							F26	No Health Consequences or Impact	A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Unexpected Reset			
									A00908	Incorrect, Inadequate or Imprecise Result or Readings			
									A160503	Inappropriate or Imprecise Result or Readings			

						CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A109503	Inappropriate or Unexpected Reset		
								F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A160503	Inappropriate or Unexpected Reset		
						CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
								F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A160503	Inappropriate or Unexpected Reset		
						CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
								F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A160503	Inappropriate or Unexpected Reset		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A160503	Inappropriate or Unexpected Reset		
3873	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A109503	Inappropriate or Unexpected Reset			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1145	Cardiovascular devices	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1233	Surgical	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E0601	Arrhythmia	A070909	Oversensing			
								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		

						F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3006	Implantable inorganic material	E0601	Arrhythmia	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	
					CT3007	Implantable ceramic	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT314	Electrically powered	E0601	Arrhythmia	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	
					CT321	Long-term surgical invasive	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT449	Generators and associated devices	E0601	Arrhythmia	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	
					CT981	Single use	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT983	Surgical invasive	E0601	Arrhythmia	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
3874	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	

				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		

						CT2407	Active implantable	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT258	Implantable defibrillators	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT2727	Active implant devices/ancillaries	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT2750	implantable cardiac electrical stimulators and associated devices	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT2966	Implantable cardiac electrical stimulators	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT2985	Active	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT3001	Implantable metal	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT3002	implantable synthetic polymer	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT3006	Implantable inorganic material	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT3007	Implantable ceramic	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT3134	Electrically powered	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT321	Long-term surgical invasive	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT449	Generators and associated devices	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT981	Single use	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
						CT983	Surgical invasive	E2403 F12 F23	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Unexpected Medical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery				
3877	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
						CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation				
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
						CT1150	Defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation				
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
						CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation				
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
						CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation				
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
						CT233	Surgical	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation				
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
						CT2406	Implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation				
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation					
						CT2407	Active implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation				

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								A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
3878	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/08/2022	02/08/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/08/2022	02/08/2022	
3879	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery			
						F24	Insufficient Health Impact Information	A0705	Battery Problem			
								A070504	Premature Discharge of Battery			

					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3885	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3886	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		

CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT1150	Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT1150	Defibrillators	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT145	Cardiovascular devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT2406	Implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	30/11/2022	30/11/2022
				A070504	Premature Discharge of Battery	30/11/2022	30/11/2022
CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	30/11/2022	30/11

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						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
3891	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/12/2021	10/12/2021	

3892	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
						F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm			
						F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
3893	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A070910	Undersensing		
							A0712	Pacing Problem				
							A071202	Inaccurate Synchronization				
						E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							A0712	Pacing Problem				
							A071202	Inaccurate Synchronization				
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
							A0712	Pacing Problem				
							A071202	Inaccurate Synchronization				
						F15	Recognized Device or Procedural Complication	A070910	Undersensing			
							A0712	Pacing Problem				
							A071202	Inaccurate Synchronization				
					CT1150	Defibrillators	E0601	Arrhythmia	A070910	Undersensing		
							A0712	Pacing Problem				
							A071202	Inaccurate Synchronization				
						E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							A0712	Pacing Problem				

				A071202	Inaccurate Synchronization		
				A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT145	Cardiovascular devices	E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT233	Surgical	E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2406	Implantable	E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2407	Active implantable	E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT258	Implantable defibrillators	E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A070910	Undersensing		

			A0712	Pacing Problem			
C12750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712 Pacing Problem			
			A071202	Inaccurate Synchronization			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070910 Undersensing			
			A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
			A0712	Pacing Problem			
C12866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712 Pacing Problem			
			A071202	Inaccurate Synchronization			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070910 Undersensing			
			A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
C12985	Active	E0601	Arrhythmia	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712 Pacing Problem			
			A071202	Inaccurate Synchronization			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070910 Undersensing			
			A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
C13001	Implantable metal	E0601	Arrhythmia	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712 Pacing Problem			
			A071202	Inaccurate Synchronization			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070910 Undersensing			
			A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
C13002	Implantable synthetic polymer	E0601	Arrhythmia	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712 Pacing Problem			
			A071202	Inaccurate Synchronization			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070910 Undersensing			
			A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
C13006	Implantable inorganic material	E0601	Arrhythmia	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712 Pacing Problem			
			A071202	Inaccurate Synchronization			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070910 Undersensing			
			A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
C13007	Implantable ceramic	E0601	Arrhythmia	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712 Pacing Problem			
			A071202	Inaccurate Synchronization			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070910 Undersensing			
			A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
C1314	Electrically powered	E0601	Arrhythmia	A071202 Inaccurate Synchronization			
			A070910	Undersensing			
			A0712	Pacing Problem			
			A071202	Inaccurate Synchronization			

3894	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					E0601	Arrhythmia	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					E2403	No Clinical Signs, Symptoms or Conditions	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					CT1449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					CT0981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					CT0983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A070910	Undersensing		
					CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT233	Surgical	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT2406	Implantable	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT2985	Active	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3695	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	22/12/2021	22/12/2021
									A070504	Premature Discharge of Battery	22/12/2021	22/12/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2021	22/12/2021

CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		F1905	Device Revision or Replacement	A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		E2104	Electric Shock	A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
	F1905	Device Revision or Replacement	A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
		CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Overensensing	04/08/2022	04/08/2022
						A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
						A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
E2403				No Clinical Signs, Symptoms or Conditions	A070909	Overensensing	04/08/2022	04/08/2022	
					A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022	
					A090801	Signal Artifact/Noise	04/08/2022	04/08/2022	
F08	Hospitalization or Prolonged Hospitalization			A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
F1905	Device Revision or Replacement		A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
	CT1233		Surgical	E2104	Electric Shock	A070909	Overensensing	04/08/2022	04/08/2022
						A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
						A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
		E2403		No Clinical Signs, Symptoms or Conditions	A070909	Overensensing	04/08/2022	04/08/2022	
					A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022	
					A090801	Signal Artifact/Noise	04/08/2022	04/08/2022	
F08		Hospitalization or Prolonged Hospitalization		A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
F1905		Device Revision or Replacement	A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
		CT12406	Implantable	E2104	Electric Shock	A070909	Overensensing	04/08/2022	04/08/2022
						A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
						A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
	E2403			No Clinical Signs, Symptoms or Conditions	A070909	Overensensing	04/08/2022	04/08/2022	
					A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022	
					A090801	Signal Artifact/Noise	04/08/2022	04/08/2022	
F08	Hospitalization or Prolonged Hospitalization			A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
F1905	Device Revision or Replacement		A070909	Overensensing	04/08/2022	04/08/2022			
			A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022			
			A090801	Signal Artifact/Noise	04/08/2022	04/08/2022			
	CT12407		Active implantable	E2104	Electric Shock	A070909	Overensensing	04/08/2022	04/08/2022
						A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
						A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
		E2403		No Clinical Signs, Symptoms or Conditions	A070909	Overensensing	04/08/2022	04/08/2022	
					A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022	
					A090801	Signal Artifact/Noise	04/08/2022	04/08/2022	
F08		Hospitalization or Prolonged Hospitalization		A070909	Overensensing	04/08/2022	04/08/2022		
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		

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		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
CT2985	Active	E2104	Electric Shock	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
		A070909	Oversensing	04/08/2022	04/08/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022		
		A090801	Signal Artifact/Noise	04/08/2022	04/08/2022		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
				A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/08/2022	04/08/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	04/08/2022	04/08/2022
				A090801	Signal Artifact/Noise	04/08/2022	04/08/2022

						F1904	Device Repositioning	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation Device Dislodged or Dislocated Oversensing Inappropriate/inadequate Shock/Stimulation Device Dislodged or Dislocated Oversensing Inappropriate/inadequate Shock/Stimulation		
						P2203	Imaging Required	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation Device Dislodged or Dislocated Oversensing Inappropriate/inadequate Shock/Stimulation		
3899	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing			
3900	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			
					CT1150	Defibrillators	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			
					CT1141	Electrodes/Leads and associated devices	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			
					CT1145	Cardiovascular devices	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			
					CT1233	Surgical	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			
					CT12406	Implantable	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			
					CT12407	Active implantable	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			
					CT258	implantable defibrillators	E0601 E2403 F26	Arrhythmia No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070912 A071302 A070909 A070912 A071302	Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation Oversensing Incorrect Interpretation of Signal Inappropriate/inadequate Shock/Stimulation			

				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
C1263	Cardiographs and associated devices	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
C12726	Physiological monitoring/measuring devices	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
C12727	Active implant devices/ancillaries	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
C12750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
C12866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
C12985	Active	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3001	Implantable metal	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3006	Implantable inorganic material	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F26	No Health Consequences or Impact	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3007	Implantable ceramic	E0601	Arrhythmia	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070912	Incorrect Interpretation of Signal				
				A071302	Inappropriate/Inadequate Shock/Stimulation				

3902	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F08	No Health Consequences or Impact	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022

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				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F22	Unexpected Diagnostic Intervention	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F2306	Resuscitation	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
CT3002	Implantable synthetic polymer	E060110	Ventricular Fibrillation	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		E2104	Electric Shock	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F22	Unexpected Diagnostic Intervention	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F2306	Resuscitation	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
CT3006	Implantable inorganic material	E060110	Ventricular Fibrillation	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		E2104	Electric Shock	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F22	Unexpected Diagnostic Intervention	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F2306	Resuscitation	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
CT3007	Implantable ceramic	E060110	Ventricular Fibrillation	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		E2104	Electric Shock	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F22	Unexpected Diagnostic Intervention	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F2306	Resuscitation	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
CT314	Electrically powered	E060110	Ventricular Fibrillation	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		E2104	Electric Shock	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A072201	High Impedance	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
		F22	Unexpected Diagnostic Intervention	A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021

						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F2306	Resuscitation		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
CT321	Long-term surgical invasive		E060110	Ventricular Fibrillation		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E2104	Electric Shock		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E2403	No Clinical Signs, Symptoms or Conditions		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F08	Hospitalization or Prolonged Hospitalization		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F1905	Device Revision or Replacement		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F22	Unexpected Diagnostic Intervention		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
CT449	Generators and associated devices		F2306	Resuscitation		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E060110	Ventricular Fibrillation		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E2104	Electric Shock		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E2403	No Clinical Signs, Symptoms or Conditions		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F08	Hospitalization or Prolonged Hospitalization		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F1905	Device Revision or Replacement		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
CT981	Single use		F22	Unexpected Diagnostic Intervention		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E060110	Ventricular Fibrillation		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E2104	Electric Shock		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E2403	No Clinical Signs, Symptoms or Conditions		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F08	Hospitalization or Prolonged Hospitalization		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F1905	Device Revision or Replacement		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
CT983	Surgical invasive		F22	Unexpected Diagnostic Intervention		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F2306	Resuscitation		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E060110	Ventricular Fibrillation		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E2104	Electric Shock		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			E2403	No Clinical Signs, Symptoms or Conditions		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
			F08	Hospitalization or Prolonged Hospitalization		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021
						A072201	High Impedance	08/12/2021	08/12/2021
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021
	F1905	Device Revision or Replacement		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021		
				A072201	High Impedance	08/12/2021	08/12/2021		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021		
	F22	Unexpected Diagnostic Intervention		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021		
				A072201	High Impedance	08/12/2021	08/12/2021		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021		
	F2306	Resuscitation		A071201	Failure to Convert Rhythm	08/12/2021	08/12/2021		
				A072201	High Impedance	08/12/2021	08/12/2021		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/12/2021	08/12/2021		

3905	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
									A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	19/01/2022	19/01/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/01/2022	19/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/01/2022	19/01/2022

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CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/04/2022	04/04/2022
CT1226	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/04/2022	04/04/2022
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/04/2022	04/04/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/04/2022	04/04/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/04/2022	04/04/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/04/2022	04/04/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/04/2022	04/04/2022
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
				A0705	Battery Problem	04/04/2022	04/04/2022
				A070504	Premature Discharge of Battery	04/04/2022	04/04/2022

3910	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT983	Surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	04/04/2022	04/04/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/04/2022	04/04/2022
					CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/04/2022	04/04/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	17/01/2022	17/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	17/01/2022	17/01/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	17/01/2022	17/01/2022
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	17/01/2022	17/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	17/01/2022	17/01/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	17/01/2022	17/01/2022
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	17/01/2022	17/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
					CT233	Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem	17/01/2022	17/01/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	17/01/2022	17/01/2022
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	17/01/2022	17/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	17/01/2022	17/01/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	17/01/2022	17/01/2022
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022
E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	17/01/2022			17/01/2022					
F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/01/2022			17/01/2022					
CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	17/01/2022	17/01/2022					
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	17/01/2022	17/01/2022					
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022					
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	17/01/2022	17/01/2022					
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022					
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	17/01/2022	17/01/2022					
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	17/01/2022	17/01/2022					
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022					
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	17/01/2022	17/01/2022					
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022					
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0705	Battery Problem	17/01/2022	17/01/2022					
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2022	17/01/2022					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	17/01/2022	17/01/2022					

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					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
3913	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A072201	High Impedance		

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					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/04/2022	21/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/04/2022	21/04/2022
									A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/04/2022	21/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/04/2022	21/04/2022
									A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/04/2022	21/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/04/2022	21/04/2022
									A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/04/2022	21/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/04/2022	21/04/2022
									A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/04/2022	21/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/04/2022	21/04/2022
									A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/04/2022	21/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/04/2022	21/04/2022
									A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/04/2022	21/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/04/2022	21/04/2022
									A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	21/04/2022	21/04/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	21/04/2022	21/04/2022
									A070504	Premature Discharge of Battery	21/04/2022	21/04/2022
3916	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022
									A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022
									A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022
									A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022
									A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022
									A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022
									A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022

CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
				A0705	Battery Problem	08/02/2022	08/02/2022
				F1905	Device Revision or Replacement	08/02/2022	08/02/2022

							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2022	08/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2022	08/02/2022
									A070504	Premature Discharge of Battery	08/02/2022	08/02/2022
3917	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A071302	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712	Oversensing Pacing Problem		

		F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2303	Medication Required	A070909	Oversensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		

								A0712	Pacing Problem		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
						F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing	
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
						F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing	
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
						F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
3918	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A23	Use of Device Problem	
							F26	No Health Consequences or Impact	A23	Use of Device Problem	
3919	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
3920	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		

		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A070909	Overensing				
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2985	Active	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3001	Implantable metal	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3008	Implantable inorganic material	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				

							E2403	No Clinical Signs, Symptoms or Conditions	A071302 A070909 A071302	Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
3921	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1233	Surgical	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT12406	Implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT12407	Active implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
CT1258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
CT1263	Cardiographs and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
CT12726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
CT12727	Active implant devices/ancillaries	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
CT12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
CT12866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation							

					CT2985	Active	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
30/22	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			

CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2104	Electric Shock	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal						
		A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
CT233	Surgical	E2104	Electric Shock	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		CT2406	Implantable	E2104	Electric Shock	A1301	Failure to Read Input Signal		
						A070909	Overensing		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
E2403	No Clinical Signs, Symptoms or Conditions			A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2407	Active implantable			E2104	Electric Shock	A1301	Failure to Read Input Signal		
						A070909	Overensing		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		CT258	Implantable defibrillators	E2104	Electric Shock	A1301	Failure to Read Input Signal		
						A070909	Overensing		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
E2403	No Clinical Signs, Symptoms or Conditions			A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT263	Cardiographs and associated devices			E2104	Electric Shock	A1301	Failure to Read Input Signal		
						A070909	Overensing		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A1301	Failure to Read Input Signal		
						A070909	Overensing		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
E2403	No Clinical Signs, Symptoms or Conditions			A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2727	Active implant devices/ancillaries			E2104	Electric Shock	A1301	Failure to Read Input Signal		
						A070909	Overensing		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A1301	Failure to Read Input Signal		
						A070909	Overensing		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
E2403	No Clinical Signs, Symptoms or Conditions			A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A1301	Failure to Read Input Signal				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2868	Implantable cardiac electrical stimulators			E2104	Electric Shock	A1301	Failure to Read Input Signal		
						A070909	Overensing		

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						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3001	Implantable metal	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3002	Implantable synthetic polymer	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3006	Implantable inorganic material	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	E0623	Unspecified Heart Problem	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
3527	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/01/2022	05/01/2022
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/01/2022	05/01/2022	
3528	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2885	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			

					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3029	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A070101	Failure to Capture		
									A070909	Oversensing		
3930	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT3134	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/12/2022	06/12/2022
3931	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/12/2022	28/12/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
									A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022

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					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F1903	Device Explanation	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F1903	Device Explanation	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F1903	Device Explanation	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F1903	Device Explanation	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F1903	Device Explanation	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F1903	Device Explanation	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F1903	Device Explanation	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/12/2022	28/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
							F1903	Device Explanation	A0705	Battery Problem	28/12/2022	28/12/2022
									A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
3932	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A070504	Premature Discharge of Battery	28/12/2022	28/12/2022
									A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2330	Pain	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
3933	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

					CT2985	Active	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3934	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A1301	Failure to Read Input Signal		

						F26	No Health Consequences or Impact	A23 A070504 A1301 A23	Use of Device Problem Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
						F26	No Health Consequences or Impact	A070504 A1301 A23	Premature Discharge of Battery Failure to Read Input Signal Use of Device Problem		
3935	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302 A0722 A072201	Inappropriate/Inadequate Shock/Stimulation Impedance Problem High Impedance	
						E2403	No Clinical Signs, Symptoms or Conditions	A071302 A0722 A072201	Inappropriate/Inadequate Shock/Stimulation Impedance Problem High Impedance		
						F08	Hospitalization or Prolonged Hospitalization	A071302 A0722 A072201	Inappropriate/Inadequate Shock/Stimulation Impedance Problem High Impedance		
						F2303	Medication Required	A071302 A0722 A072201	Inappropriate/Inadequate Shock/Stimulation Impedance Problem High Impedance		
				CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		

				A0722	Impedance Problem			
				A072201	High Impedance			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
CT1145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
CT1233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
CT12406	Implantable	E2104	Electric Shock	A072201	High Impedance			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
CT12407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
CT1258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A0722	Impedance Problem			
				A072201	High Impedance			

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CT3002	Implantable synthetic polymer	E2104	Electric Shock	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F2303	Medication Required	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
CT3006	Implantable inorganic material	E2104	Electric Shock	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F2303	Medication Required	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
CT3007	Implantable ceramic	E2104	Electric Shock	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F2303	Medication Required	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
CT314	Electrically powered	E2104	Electric Shock	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F2303	Medication Required	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
CT321	Long-term surgical invasive	E2104	Electric Shock	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F2303	Medication Required	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
CT449	Generators and associated devices	E2104	Electric Shock	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F2303	Medication Required	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
CT981	Single use	E2104	Electric Shock	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		F2303	Medication Required	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
CT983	Surgical invasive	E2104	Electric Shock	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0722	Impedance Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

									A0722	Impedance Problem		
						F08	Hospitalization or Prolonged Hospitalization		A072201	High Impedance		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0722	Impedance Problem		
						F2303	Medication Required		A072201	High Impedance		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0722	Impedance Problem		
									A072201	High Impedance		
3636	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3637	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	11/01/2022	11/01/2022

			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
			A0705	Battery Problem	A070504	Battery Problem	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A0705	Battery Problem	11/01/2022	11/01/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A0705	Battery Problem	11/01/2022	11/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	11/01/2022
			A0705	Battery Problem	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	11/01/2022
			A0705	Battery Problem	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	11/01/2022	11/01/2022	11/01/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	11/01/2022
			A0705	Battery Problem	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F1905	Device Revision or Replacement	A070504	Battery Problem	11/01/2022	11/01/2022	11/01/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	11/01/2022
			A0705	Battery Problem	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	11/01/2022
			A0705	Battery Problem	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	11/01/2022
			A0705	Battery Problem	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	11/01/2022
			A0705	Battery Problem	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2022
			A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022	11/01/2

								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/01/2022	11/01/2022
									A070504	Battery Problem	11/01/2022	11/01/2022	
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
								F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
								F1905	Device Revision or Replacement	A0705	Battery Problem	11/01/2022	11/01/2022
									A070504	Premature Discharge of Battery	11/01/2022	11/01/2022	
3938	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
3939	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A0709 A070909 A071302 A1301	Failure to Read Input Signal Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT145	Cardiovascular devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT233	Surgical	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT246	Implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT247	Active implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		

CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
3941	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070909	Oversensing		
									A071204	No Pacing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071204	No Pacing		
3942	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3943	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F24	Insufficient Health Impact Information	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F24	Insufficient Health Impact Information	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F24	Insufficient Health Impact Information	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F24	Insufficient Health Impact Information	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F24	Insufficient Health Impact Information	A0705	Battery Problem	15/09/2022	15/09/2022	
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022	

				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
				A0705	Battery Problem	15/09/2022	15/09/2022
				A070504	Premature Discharge of Battery	15/09/2022	15/09/2022
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2022	15

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						CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem								
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem								
								F23	Unexpected Medical Intervention	A0705	Battery Problem								
						3952	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
														A070909	Oversensing	11/07/2022	11/07/2022		
											CT11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
														A070909	Oversensing	11/07/2022	11/07/2022		
											CT11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
														A070909	Oversensing	11/07/2022	11/07/2022		
											CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
											CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
														A070909	Oversensing	11/07/2022	11/07/2022		
											CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
														A070909	Oversensing	11/07/2022	11/07/2022		
											CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
														A070909	Oversensing	11/07/2022	11/07/2022		
											CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
														A070909	Oversensing	11/07/2022	11/07/2022		
											CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022	
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		
												F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022		

CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
CT2726	Physiological monitoring/measuring devices	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
CT2866	Implantable cardiac electrical stimulators	F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT3002	Implantable synthetic polymer	F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT3007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT314	Electrically powered	F1903	Device Explanation	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT449	Generators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
CT983	Surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022
				A070504	Premature Discharge of Battery	11/07/2022	11/07/2022
				A070909	Oversensing	11/07/2022	11/07/2022

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT081	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
					CT083	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2022	31/01/2022
3955	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3956	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A0508	Noise, Audible		
									A090801	Signal Artifact/Noise		
									A0508	Noise, Audible		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A0508	Noise, Audible		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A0508	Noise, Audible		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A0508	Noise, Audible		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A0508	Noise, Audible		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		

CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2407	Active Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A072201	High Impedance		

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CT1147	Defibrillators and associated devices	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT1150	Defibrillators	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT1145	Cardiovascular devices	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT1233	Surgical	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT12406	Implantable	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT12407	Active implantable	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT1258	Implantable defibrillators	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT1263	Cardiographs and associated devices	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT12726	Physiological monitoring/measuring devices	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT12727	Active implant devices/ancillaries	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT12866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT12985	Active	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT13001	Implantable metal	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT13002	Implantable synthetic polymer	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT13006	Implantable inorganic material	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT13007	Implantable ceramic	E2104	Electric Shock	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F17	Sedation	A072201	High Impedance		
		F2203	Imaging Required	A072201	High Impedance		
		F26	No Health Consequences or Impact	A072201	High Impedance		

					CT314	Electrically powered	F26 E2104 E2403 F17 F2203 F26	No Health Consequences or Impact Electric Shock No Clinical Signs, Symptoms or Conditions Sedation Imaging Required No Health Consequences or Impact	A072201 A072201 A072201 A072201 A072201 A072201	High Impedance High Impedance High Impedance High Impedance High Impedance High Impedance		
					CT321	Long-term surgical invasive	E2104 E2403 F17 F2203 F26	Electric Shock No Clinical Signs, Symptoms or Conditions Sedation Imaging Required No Health Consequences or Impact	A072201 A072201 A072201 A072201 A072201	High Impedance High Impedance High Impedance High Impedance High Impedance		
					CT449	Generators and associated devices	F26 E2104 E2403 F17 F2203 F26	No Health Consequences or Impact Electric Shock No Clinical Signs, Symptoms or Conditions Sedation Imaging Required No Health Consequences or Impact	A072201 A072201 A072201 A072201 A072201 A072201	High Impedance High Impedance High Impedance High Impedance High Impedance High Impedance		
					CT981	Single use	E2104 E2403 F17 F2203 F26	Electric Shock No Clinical Signs, Symptoms or Conditions Sedation Imaging Required No Health Consequences or Impact	A072201 A072201 A072201 A072201 A072201	High Impedance High Impedance High Impedance High Impedance High Impedance		
					CT983	Surgical invasive	E2104 E2403 F17 F2203 F26	Electric Shock No Clinical Signs, Symptoms or Conditions Sedation Imaging Required No Health Consequences or Impact	A072201 A072201 A072201 A072201 A072201	High Impedance High Impedance High Impedance High Impedance High Impedance		
3960	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26 E2403 F08 F1905	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A072201 A0705 A070504 A0705	High Impedance Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT1147	Defibrillators and associated devices	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT1160	Defibrillators	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT141	Electrodes/Leads and associated devices	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT145	Cardiovascular devices	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT233	Surgical	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT2406	Implantable	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT2407	Active implantable	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT258	Implantable defibrillators	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT263	Cardiographs and associated devices	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A070504 A0705	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	04/02/2022 04/02/2022 04/02/2022 04/02/2022	04/02/2022 04/02/2022 04/02/2022 04/02/2022
					CT2726	Physiological monitoring/measuring devices	F08 E2403	Hospitalization or Prolonged Hospitalization No Clinical Signs, Symptoms or Conditions	A0705 A0705	Battery Problem Battery Problem	04/02/2022 04/02/2022	04/02/2022 04/02/2022

					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
3962	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
3963	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F22	Unexpected Diagnostic Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
3964	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/11/2022	21/11/2022
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/11/2022	21/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/11/2022	21/11/2022

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						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
					CT321	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
					CT449	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
					CT981	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
					CT983	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
						F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	27/10/2022	27/10/2022
3066	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	26/01/2022	26/01/2022
								A17	Compatibility Problem	26/01/2022	26/01/2022
						F23	Unexpected Medical Intervention	A160503	Inappropriate or Unexpected Reset	26/01/2022	26/01/2022
								A17	Compatibility Problem	26/01/2022	26/01/2022
3067	2022	All other reportable incidents			CT258	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/09/2022	21/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/09/2022	21/09/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/09/2022	21/09/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/09/2022	21/09/2022
3068	2022	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT1147	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
								A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT1141	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
								A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT1145	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT1233	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
								A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT2408	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT2407	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT1263	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	02/02/2022	02/02/2022
								A070504	Premature Discharge of Battery	02/02/2022	02/02/2022
					CT12726	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2022	02/02/2022

CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1145	Cardiovascular devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
3970	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F26	No Health Consequences or Impact	A0713	Defibrillation/Stimulation Problem		
3971	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance			
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
3972	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2117	Twiddlers Syndrome	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2117	Twiddlers Syndrome	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2104	Electric Shock	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2117	Twiddlers Syndrome	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2117	Twiddlers Syndrome	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
					CT1145	Cardiovascular devices	E2104	Electric Shock	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2117	Twiddlers Syndrome	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
					CT1233	Surgical	E2104	Electric Shock	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			
							E2117	Twiddlers Syndrome	A010402	Migration			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal			

				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2406	Implantable	E2104	Electric Shock	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2407	Active implantable	E2104	Electric Shock	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
				A070909	Oversensing		

CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2117	Twiddlers Syndrome	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2117	Twiddlers Syndrome	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
CT2806	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2117	Twiddlers Syndrome	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2117	Twiddlers Syndrome	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2117	Twiddlers Syndrome	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		E2117	Twiddlers Syndrome	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		

CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A010402	Migration		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A010402	Migration		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		E2117	Twiddlers Syndrome	A010402	Migration		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT981	Single use	E2104	Electric Shock	A010402 A070909 A071302 A1301	Migration Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							E2117	Twiddlers Syndrome	A010402 A070909 A071302 A1301	Migration Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302 A1301	Migration Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302 A1301	Migration Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT983	Surgical invasive	E2104	Electric Shock	A010402 A070909 A071302 A1301	Migration Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							E2117	Twiddlers Syndrome	A010402 A070909 A071302 A1301	Migration Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A071302 A1301	Migration Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402 A070909 A071302 A1301	Migration Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
3973	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			

					CT3001	Implantable metal	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104 E2403 F10	Electric Shock No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
3974	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT1147	Defibrillators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT1150	Defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT145	Cardiovascular devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT233	Surgical	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT2406	Implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT2407	Active implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT263	Cardiographs and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT2727	Active implant devices/ancillaries	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT2985	Active	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT3001	Implantable metal	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT3002	Implantable synthetic polymer	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT3006	Implantable inorganic material	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT3007	Implantable ceramic	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT314	Electrically powered	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT321	Long-term surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT449	Generators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT981	Single use	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
					CT983	Surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
3975	2022		37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	16/09/2022 16/09/2022	16/09/2022 16/09/2022
					CT1150	Defibrillators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	16/09/2022 16/09/2022	16/09/2022 16/09/2022
					CT141	Electrodes/Leads and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	16/09/2022 16/09/2022	16/09/2022 16/09/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/09/2022	16/09/2022

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F2203	Imaging Required	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F2203	Imaging Required	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F2203	Imaging Required	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F2203	Imaging Required	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F2203	Imaging Required	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F2203	Imaging Required	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
9977	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A070910	Undersensing		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
					CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
					CT1150	Defibrillators	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
					CT145	Cardiovascular devices	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
					CT233	Surgical	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
					CT2406	Implantable	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
					CT2407	Active implantable	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
									A0909	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		

CT263	Cardiographs and associated devices	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT2985	Active	F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT3002	Implantable synthetic polymer	E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT3006	Implantable inorganic material	E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E060110	Ventricular Fibrillation	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		F26	No Health Consequences or Impact	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		
		E0601	Arrhythmia	A070910	Unexpected Therapeutic Results		
				A0909	Undersensing		

					CT321	Long-term surgical invasive	E0601	Arrhythmia	A070910	Undersensing		
							E060110	Ventricular Fibrillation	A0909	Unexpected Therapeutic Results		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0909	Unexpected Therapeutic Results		
									A070910	Undersensing		
					CT449	Generators and associated devices	E0601	Arrhythmia	A070910	Undersensing		
									A0909	Unexpected Therapeutic Results		
							E060110	Ventricular Fibrillation	A070910	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A0909	Unexpected Therapeutic Results		
					CT981	Single use	E0601	Arrhythmia	A070910	Undersensing		
							E060110	Ventricular Fibrillation	A0909	Unexpected Therapeutic Results		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0909	Unexpected Therapeutic Results		
									A070910	Undersensing		
									A0909	Unexpected Therapeutic Results		
					CT983	Surgical invasive	E0601	Arrhythmia	A070910	Undersensing		
							E060110	Ventricular Fibrillation	A0909	Unexpected Therapeutic Results		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0909	Unexpected Therapeutic Results		
3978	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3979	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
3980	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071101	Difficult to Interrogate		
							F08	Hospitalization or Prolonged Hospitalization	A071101	Difficult to Interrogate		
							F23	Unexpected Medical Intervention	A071101	Difficult to Interrogate		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071101	Difficult to Interrogate		
							F08	Hospitalization or Prolonged Hospitalization	A071101	Difficult to Interrogate		
							F23	Unexpected Medical Intervention	A071101	Difficult to Interrogate		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071101	Difficult to Interrogate		

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CT1150	Defibrillators	F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT1233	Surgical	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT12406	Implantable	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022

CT2407	Active implantable	F2203	Imaging Required	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		E2104	Electric Shock	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		F2203	Imaging Required	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
CT263	Cardiographs and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
		F2203	Imaging Required	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
				A070909	Overensing	13/09/2022	13/09/202

				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT2985	Active	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022

CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022	
			A090801	Signal Artifact/Noise	13/09/2022	13/09/2022	
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT3007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
	F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022	
			A090801	Signal Artifact/Noise	13/09/2022	13/09/2022	
		F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022	
			A090801	Signal Artifact/Noise	13/09/2022	13/09/2022	
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022		
		A090801	Signal Artifact/Noise	13/09/2022	13/09/2022		
	F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022	
			A090801	Signal Artifact/Noise	13/09/2022	13/09/2022	
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022	
			A090801	Signal Artifact/Noise	13/09/2022	13/09/2022	
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
F1905	Device Revision or Replacement	A070909	Oversensing	13/09/2022	13/09/2022		
		A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022		
		A090801	Signal Artifact/Noise	13/09/2022	13/09/2022		
	F2203	Imaging Required	A070909	Oversensing	13/09/2022	13/09/2022	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022	
			A090801	Signal Artifact/Noise	13/09/2022	13/09/2022	
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022
	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	13/09/2022	13/09/2022	
			A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022	
			A090801	Signal Artifact/Noise	13/09/2022	13/09/2022	
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/09/2022	13/09/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	13/09/2022	13/09/2022
				A090801	Signal Artifact/Noise	13/09/2022	13/09/2022

					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
3983	2022	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
3984	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2340	Wound Dehiscence	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1904	Device Repositioning	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2340	Wound Dehiscence	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1904	Device Repositioning	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2340	Wound Dehiscence	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1904	Device Repositioning	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2340	Wound Dehiscence	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1904	Device Repositioning	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2340	Wound Dehiscence	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1904	Device Repositioning	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2340	Wound Dehiscence	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1904	Device Repositioning	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2340	Wound Dehiscence	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

CT2407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
		F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2340	Wound Dehiscence	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
	F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2340	Wound Dehiscence	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
CT263	Cardiographs and associated devices	E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Overensing		
E2340			Wound Dehiscence	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
E2401		Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
E2403		No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
F08		Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
CT2727	Active implant devices/ancillaries	F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
	E2340	Wound Dehiscence	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
		F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2340	Wound Dehiscence	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
	F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				
	E2340	Wound Dehiscence	A071302	Inappropriate/Inadequate Shock/Stimulation				
			A070909	Overensing				

CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
		E2340	Wound Dehiscence	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3001	Implantable metal	F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2340	Wound Dehiscence	A070909	Oversensing		
		E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer			A070909	Oversensing		
		F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2340	Wound Dehiscence	A070909	Oversensing		
		E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
CT3006	Implantable inorganic material	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2340	Wound Dehiscence	A070909	Oversensing		
		E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2340	Wound Dehiscence	A070909	Oversensing		
CT314	Electrically powered	E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2340	Wound Dehiscence	A070909	Oversensing		
		E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F1904	Device Repositioning	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2340	Wound Dehiscence	A070909	Oversensing		
		E2401	Insufficient Information	A071302	Inappropriate/Inadequate Shock/Stimulation		

								E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
								A070909	Oversensing				
								F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/inadequate Shock/Stimulation		
								A070908	Oversensing				
								F1904	Device Repositioning	A071302	Inappropriate/inadequate Shock/Stimulation		
								A070909	Oversensing				
								A071302	Inappropriate/inadequate Shock/Stimulation				
								A070909	Oversensing				
								A071302	Inappropriate/inadequate Shock/Stimulation				
								A070909	Oversensing				
								A071302	Inappropriate/inadequate Shock/Stimulation				
								A070909	Oversensing				
						CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
						A070909	Oversensing						
						E2340	Wound Dehiscence	A071302	Inappropriate/inadequate Shock/Stimulation				
						A070909	Oversensing						
						E2401	Insufficient Information	A071302	Inappropriate/inadequate Shock/Stimulation				
						A070909	Oversensing						
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation				
						A070909	Oversensing						
						F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/inadequate Shock/Stimulation				
						A070909	Oversensing						
						F1904	Device Repositioning	A071302	Inappropriate/inadequate Shock/Stimulation				
						A070909	Oversensing						
A071302	Inappropriate/inadequate Shock/Stimulation												
CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing								
A071302	Inappropriate/inadequate Shock/Stimulation												
E2340	Wound Dehiscence	A070909	Oversensing										
A071302	Inappropriate/inadequate Shock/Stimulation												
E2401	Insufficient Information	A071302	Inappropriate/inadequate Shock/Stimulation										
A070909	Oversensing												
E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing										
A071302	Inappropriate/inadequate Shock/Stimulation												
F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/inadequate Shock/Stimulation										
A070909	Oversensing												
F1904	Device Repositioning	A071302	Inappropriate/inadequate Shock/Stimulation										
A070909	Oversensing												
A071302	Inappropriate/inadequate Shock/Stimulation												
3985	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A070504	Premature Discharge of Battery			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
3986	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal			
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			

						F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070912	Incorrect Interpretation of Signal		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Inappropriate/Inadequate Shock/Stimulation	
								A071302	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
3987	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Racing Problem	
								A0712	Racing Problem		
3988	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F26	No Health Consequences or Impact	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F26	No Health Consequences or Impact	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F26	No Health Consequences or Impact	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F26	No Health Consequences or Impact	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2022	08/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/11/2022
								A070504	Premature Discharge of Battery	08/11/2022	08/11/2022

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			L-exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT981	Single use	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT983	Surgical invasive	E2104	Electric Shock	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
3990	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A072201	Battery Problem High Impedance		
							F26	No Health Consequences or Impact	A0705 A072201	Battery Problem High Impedance		
3991	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT233	Surgical	E2104	Electric Shock	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		

				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT2406	Implantable			A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT2407	Active implantable			A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT258	Implantable defibrillators			A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT263	Cardiographs and associated devices			A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT2726	Physiological monitoring/measuring devices			A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT2727	Active implant devices/ancillaries			A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A070910	Undersensing			

				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT3007	Implantable ceramic	E2104	Electric Shock		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT314	Electrically powered	E2104	Electric Shock		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT321	Long-term surgical invasive	E2104	Electric Shock		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT449	Generators and associated devices	E2104	Electric Shock		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT981	Single use	E2104	Electric Shock		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			
CT983	Surgical invasive	E2104	Electric Shock		A070909	Oversensing			
					A070910	Undersensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
					A1301	Failure to Read Input Signal			

								E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
3992	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							E2403	No Clinical Signs, Symptoms or Conditions		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							E2403	No Clinical Signs, Symptoms or Conditions		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
					CT1150	Defibrillators	E2104	Electric Shock		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							E2403	No Clinical Signs, Symptoms or Conditions		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							E2403	No Clinical Signs, Symptoms or Conditions		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
					CT1145	Cardiovascular devices	E2104	Electric Shock		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							E2403	No Clinical Signs, Symptoms or Conditions		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
					CT1233	Surgical	E2104	Electric Shock		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							E2403	No Clinical Signs, Symptoms or Conditions		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
					CT2406	Implantable	E2104	Electric Shock		A0508 A071302 A072201 A0908	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance Incorrect, Inadequate or Imprecise Result or Readings			
							E2403	No Clinical Signs, Symptoms or Conditions		A0508 A071302 A072201	Noise, Audible Inappropriate/Inadequate Shock/Stimulation High Impedance			

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CT2985	Active	E2104	Electric Shock	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0508	Noise, Audible		
CT3001	Implantable metal			A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2104	Electric Shock	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer			A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2104	Electric Shock	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT3006	Implantable inorganic material			A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2104	Electric Shock	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
CT3007	Implantable ceramic			A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2104	Electric Shock	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
CT314	Electrically powered			A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2104	Electric Shock	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive			A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2104	Electric Shock	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT449	Generators and associated devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2104	Electric Shock	A0508	Noise, Audible		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings		
		E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

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								F26	No Health Consequences or Impact	A072201	High Impedance			
			CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
			CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	No Health Consequences or Impact	A072201	High Impedance				
					F26	No Health Consequences or Impact	A072201	No Health Consequences or Impact	A072201	High Impedance				
4000	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
									A090801	Signal Artifact/Noise				
							F26	No Health Consequences or Impact	A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
									A070909	Oversensing				
									A090801	Signal Artifact/Noise				
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
									A090801	Signal Artifact/Noise				

4002	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
4003	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2458	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
4004	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A040101	Fracture		
									A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A040101	Fracture		
									A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A040101	Fracture		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A040101	Fracture		

				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

CT2985	Active	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3001	Implantable metal	F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3007	Implantable ceramic	F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT449	Generators and associated devices	F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT983	Surgical invasive	E2104	Electric Shock	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A040101	Fracture		
				A070909	Oversensing		

4005	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	25/09/2022	25/09/2022
									A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	25/09/2022	25/09/2022
									A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022
									A0508	Noise, Audible	25/09/2022	25/09/2022
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		
							A0508	Noise, Audible	25/09/2022	25/09/2022		
							A070504	Premature Discharge of Battery	25/09/2022	25/09/2022		

						F1905	Device Revision or Replacement	A0508	Noise, Audible	25/09/2022	25/09/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/09/2022
								A0508	Noise, Audible	25/09/2022	25/09/2022
4006	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT233	Surgical	E2104	Electric Shock	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2407	Active Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2407	Active Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

[illegible]

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CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Overensing		
		E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Overensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Overensing		
CT1150	Defibrillators	F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Overensing		
		E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Overensing		
		E2311	Discomfort	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E0601	Arrhythmia	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT145	Cardiovascular devices	E2311	Discomfort	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Overensing		
		E2311	Discomfort	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	F23	Unexpected Medical Intervention	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E0601	Arrhythmia	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Overensing		
CT258	Implantable defibrillators	E2311	Discomfort	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E0601	Arrhythmia	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	F23	Unexpected Medical Intervention	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Overensing		
		E2311	Discomfort	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E0601	Arrhythmia	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A070909	Oversensing		
		E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT2966	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
CT2985	Active			A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E0601	Arrhythmia	A070909	Oversensing		
		E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal			A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E0601	Arrhythmia	A070909	Oversensing		
CT3002	Implantable synthetic polymer			A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT3006	Implantable inorganic material			A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT3007	Implantable ceramic			A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT314	Electrically powered			A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT321	Long-term surgical invasive			A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT449	Generators and associated devices			A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT981	Single use			A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2311	Discomfort	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT983	Surgical invasive	E0601	Arrhythmia	A070909	Oversensing		

							E2311	Discomfort	A071302 A070909	Inappropriate/inadequate Shock/Stimulation Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302 A070908	Inappropriate/inadequate Shock/Stimulation Oversensing		
							F23	Unexpected Medical Intervention	A071302 A070909	Inappropriate/inadequate Shock/Stimulation Oversensing		
4013	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302 A110303	Inappropriate/inadequate Shock/Stimulation Program or Algorithm Execution Failure		
							F26	No Health Consequences or Impact	A110303	Program or Algorithm Execution Failure		
4014	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908 A0705 A070504	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0908 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022	13/12/2022 13/12/2022
							F1905	Device Revision or Replacement	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	13/12/2022 13/12/2022 13/12/2022	13/12/2022 13/12/2022 13/12/2022

CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	13/12/2022	13/12/2022
				A070504	Premature Discharge of Battery	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/12/2022	13/12/2022

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
4016	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4017	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
									A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022

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						F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	26/09/2022	26/09/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	26/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	26/09/2022	26/09/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	26/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	26/09/2022	26/09/2022
					CT321	Long-term surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate	26/09/2022
						F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	26/09/2022	26/09/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	26/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	26/09/2022	26/09/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	26/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	26/09/2022	26/09/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	26/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate	26/09/2022	26/09/2022
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	26/09/2022	26/09/2022
4019	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT2727	Active implant devices/anillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022

4020	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2022	27/03/2022
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
							F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022
									A070504	Premature Discharge of Battery	29/09/2022	29/09/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
		F1903	Device Explanation	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/09/2022	29/09/2022					
				A070504	Premature Discharge of Battery	29/09/2022	29/09/2022					

							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT12750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT2985	Active	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT13001	implantable metal	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT13002	Implantable synthetic polymer	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT3006	Implantable inorganic material	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT3007	Implantable ceramic	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT1314	Electrically powered	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT321	Long-term surgical invasive	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT449	Generators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT981	Single use	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
					CT983	Surgical invasive	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm	17/02/2022	17/02/2022
4022	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/11/2022	11/11/2022	
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
								A070504	Premature Discharge of Battery	11/11/2022	11/11/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022	

CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
				A0705	Battery Problem	11/11/2022	11/11/2022
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/11/2022	11/11/2022
				A070504	Premature Discharge of Battery	11/11/2022	11/11/2022

							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/11/2022	11/11/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
									A0705	Battery Problem	11/11/2022	11/11/2022
									A070504	Premature Discharge of Battery	11/11/2022	11/11/2022
4023	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
4024	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/02/2022	09/02/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/02/2022	09/02/2022
4025	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4026	2022	Unanticipated serious deterioration in state of health	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							E0602	Cardiac Arrest	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F2306	Resuscitation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							E0602	Cardiac Arrest	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F2306	Resuscitation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							E0602	Cardiac Arrest	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		

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CT2750	Implantable cardiac electrical stimulators and associated devices	F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
		F2306	Resuscitation	A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
		E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
		F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation			
		F2306	Resuscitation	A0709	Device Sensing Problem			
		CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation	
E0602	Cardiac Arrest	A0709	Device Sensing Problem					
F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation					
F1001	Absence of Treatment	A0709	Device Sensing Problem					
F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation					
F23	Unexpected Medical Intervention	A0709	Device Sensing Problem					
F2306	Resuscitation	A071301	Failure to Deliver Shock/Stimulation					
CT2985	Active	E060109	Tachycardia	A0709	Device Sensing Problem			
E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation					
F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem					
F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation					
F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem					
F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation					
F2306	Resuscitation	A0709	Device Sensing Problem					
CT3001	Implantable metal	E060109	Tachycardia	A0709	Device Sensing Problem			
E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation					
F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem					
F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation					
F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem					
F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation					
F2306	Resuscitation	A0709	Device Sensing Problem					
CT3002	Implantable synthetic polymer	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation			
E0602	Cardiac Arrest	A0709	Device Sensing Problem					
F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation					
F1001	Absence of Treatment	A0709	Device Sensing Problem					
F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation					
F23	Unexpected Medical Intervention	A0709	Device Sensing Problem					
F2306	Resuscitation	A071301	Failure to Deliver Shock/Stimulation					
CT3006	Implantable inorganic material	E060109	Tachycardia	A0709	Device Sensing Problem			
E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation					
F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem					
F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation					
F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem					
F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation					
F2306	Resuscitation	A0709	Device Sensing Problem					
CT3007	Implantable ceramic	E060109	Tachycardia	A0709	Device Sensing Problem			

							E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
							F2306	Resuscitation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
						CT314	E060109	Tachycardia	A0709	Device Sensing Problem		
							E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
							F2306	Resuscitation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
						CT321	E060109	Tachycardia	A0709	Device Sensing Problem		
							E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
							F2306	Resuscitation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
						CT449	E060109	Tachycardia	A0709	Device Sensing Problem		
							E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
							F2306	Resuscitation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
						CT981	E060109	Tachycardia	A0709	Device Sensing Problem		
							E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
							F2306	Resuscitation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
						CT983	E060109	Tachycardia	A0709	Device Sensing Problem		
							E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
							F2306	Resuscitation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
4027	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
									A071102	Failure to Interrogate		
									A070504	Premature Discharge of Battery		
									A071102	Failure to Interrogate		

		F1903	Device Explanation	A070504	Premature Discharge of Battery		
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT1150	Defibrillators	F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT1141	Electrodes/Leads and associated devices	F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT145	Cardiovascular devices	F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT2406	Implantable	F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT2407	Active implantable	F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT2726	Physiological monitoring/measuring devices	F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT2727	Active implant devices/ancillaries	F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		

CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
CT2906	Implantable cardiac electrical stimulators			A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT2985	Active	F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
CT3001	Implantable metal			A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT3002	Implantable synthetic polymer	F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
CT3006	Implantable inorganic material			A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT3007	Implantable ceramic	F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
CT314	Electrically powered			A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
CT449	Generators and associated devices			A070504	Premature Discharge of Battery		
		F1903	Device Explanation	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
CT981	Single use	F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
				A070504	Premature Discharge of Battery		
		F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
		F1903	Device Explanation	A071102	Failure to Interrogate		

4028	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate		
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A071102	Failure to Interrogate		
									A070504	Premature Discharge of Battery		
									A071102	Failure to Interrogate		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F27	Problem Identified During Non-Clinical Procedure	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F27	Problem Identified During Non-Clinical Procedure	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							

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							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
									A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT3006	implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/03/2022	09/03/2022
									A070504	Premature Discharge of Battery	09/03/2022	09/03/2022
4030	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4031	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation		
									A090805	Incorrect Measurement		
							F26	No Health Consequences or Impact	A071301	Failure to Deliver Shock/Stimulation		
									A090805	Incorrect Measurement		
4032	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1145	Cardiovascular devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A0712	Pacing Problem		

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					CT981	Single use	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4033	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4034	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070604	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		

							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
4035	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping device	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	09/02/2022	09/02/2022

					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F27	Problem Identified During Non-Clinical Procedure	A070504	Premature Discharge of Battery			
4037	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
4038	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/10/2022		17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022		17/10/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/10/2022		17/10/2022

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						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/10/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022	17/10/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/10/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022	17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/10/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022	17/10/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/10/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022	17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/10/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022	17/10/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/10/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022	17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
								A070504	Premature Discharge of Battery	17/10/2022	17/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/10/2022
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2022	17/10/2022
4039	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	

					CT321	Long-term surgical invasive	E2403	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4040	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/02/2022	16/02/2022
					F1901	Additional Surgery	A070504	Additional Surgery	A070504	Premature Discharge of Battery	16/02/2022	16/02/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/02/2022	16/02/2022
					F1901	Additional Surgery	A070504	Additional Surgery	A070504	Premature Discharge of Battery	16/02/2022	16/02/2022
4042	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	09/02/2022	09/02/2022
					F1901	Additional Surgery	A072201	Additional Surgery	A072201	High Impedance	09/02/2022	09/02/2022
4043	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
4044	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F08	Hospitalization or Prolonged Hospitalization	A070504	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F12	Serious Injury/Illness/ Impairment	A070504	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					F1903	Device Explanation	A070504	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/10/2022	12/10/2022
4045	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings		
									A0713	Defibrillation/Stimulation Problem		
									A090811	Unable to Obtain Readings		
4046	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/10/2022	19/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/10/2022	19/10/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/10/2022	19/10/2022
4047	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
									A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072201	High Impedance		

							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072201	High Impedance		
4048	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
4049	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

							F26	No Health Consequences or Impact	A07909 A1301	Failure to Read Input Signal Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A1301	Failure to Read Input Signal Oversensing		
							F26	No Health Consequences or Impact	A07909 A1301	Failure to Read Input Signal Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A1301	Failure to Read Input Signal Oversensing		
							F26	No Health Consequences or Impact	A07909 A1301	Failure to Read Input Signal Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A1301	Failure to Read Input Signal Oversensing		
							F26	No Health Consequences or Impact	A07909 A1301	Failure to Read Input Signal Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A1301	Oversensing Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A07909 A1301	Oversensing Failure to Read Input Signal		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A1301	Oversensing Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A07909 A1301	Oversensing Failure to Read Input Signal		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A1301	Oversensing Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A07909 A1301	Oversensing Failure to Read Input Signal		
4050	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
							F1908	Prolonged Surgery	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A07909 A090801	Oversensing Signal Artifact/Noise	25/01/2022	25/01/2022

						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
						F1908	Prolonged Surgery	A070909	Overensing	25/01/2022	25/01/2022
								A090801	Signal Artifact/Noise	25/01/2022	25/01/2022
4051	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT123	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
						F1905	Device Revision or Replacement	A0705	Battery Problem	16/03/2022	16/03/2022
								A070504	Premature Discharge of Battery	16/03/2022	16/03/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2022

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						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
										A070504	Battery Problem	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
										A070504	Battery Problem	31/03/2022	31/03/2022
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
										A070504	Battery Problem	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
										A070504	Battery Problem	31/03/2022	31/03/2022
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
										A070504	Battery Problem	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
										A070504	Battery Problem	31/03/2022	31/03/2022
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
										A070504	Battery Problem	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
										A070504	Battery Problem	31/03/2022	31/03/2022
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F1905	Device Revision or Replacement	A070504	Battery Problem	31/03/2022	31/03/2022
										A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
4053	2022		All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/03/2022	31/03/2022
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
4054	2022		All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/02/2022	11/02/2022
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/02/2022	11/02/2022
4055	2022		All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		

						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
				CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
4056	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance			
4057	2022		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A070602	Delayed Charge Time	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
						F02	Death	A070602	Delayed Charge Time	11/11/2022	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
					CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A070602	Delayed Charge Time	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
						F02	Death	A070602	Delayed Charge Time	11/11/2022	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
					CT1150	Defibrillators	E0601	Arrhythmia	A070602	Delayed Charge Time	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
						F02	Death	A070602	Delayed Charge Time	11/11/2022	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A070602	Delayed Charge Time	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
						F02	Death	A070602	Delayed Charge Time	11/11/2022	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
					CT145	Cardiovascular devices	E0601	Arrhythmia	A070602	Delayed Charge Time	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
						F02	Death	A070602	Delayed Charge Time	11/11/2022	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022
									A180503	Inappropriate or Unexpected Reset	11/11/2022	11/11/2022
					CT233	Surgical	E0601	Arrhythmia	A070602	Delayed Charge Time	11/11/2022	11/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	11/11/2022	11/11/2022

		F02	Death	A160503 A070602 A071302 A160503 A070602 A071302 A160503	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset	11/11/2022 11/11/2022 11/11/2022 11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT2406	Implantable	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT2407	Active implantable	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT258	Implantable defibrillators	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT263	Cardiographs and associated devices	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate or Unexpected Reset Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT2726	Physiological monitoring/measuring devices	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT2985	Active	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT3001	Implantable metal	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT3006	Implantable inorganic material	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT3007	Implantable ceramic	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT314	Electrically powered	E0601	Arrhythmia	A160503 A070602 A071302 F02	Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Death	11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022
CT321	Long-term surgical invasive	E0601	Arrhythmia	A160503 A070602	Inappropriate or Unexpected Reset Delayed Charge Time	11/11/2022 11/11/2022	11/11/2022 11/11/2022

						F02	Death	A071302 A160503 A070602 A071302 A160503	Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset	11/11/2022 11/11/2022 11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022 11/11/2022 11/11/2022
				CT1449	Generators and associated devices	E0801	Arrhythmia	A070602 A071302 A160503	Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset	11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022
						F02	Death	A070602 A071302 A160503	Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset	11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022
				CT1981	Single use	E0601	Arrhythmia	A070602 A071302 A160503	Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset	11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022
						F02	Death	A070602 A071302 A160503	Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset	11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022
				CT983	Surgical invasive	E0801	Arrhythmia	A070602 A071302 A160503	Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset	11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022
						F02	Death	A070602 A071302 A160503	Delayed Charge Time Inappropriate/Inadequate Shock/Stimulation Inappropriate or Unexpected Reset	11/11/2022 11/11/2022 11/11/2022	11/11/2022 11/11/2022 11/11/2022
4058	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010 Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT1147 Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT1150 Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT141 Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT145 Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT233 Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT2406 Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT2407 Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT258 Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT263 Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT2726 Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT2727 Active implant devices/incinerates	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT2750 Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT2866 Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT2985 Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT3001 Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT3002 Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT3006 Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT3007 Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT314 Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT321 Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT449 Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT981 Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
					CT983 Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2018	
4059	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147 Defibrillators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT1150 Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT141 Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT145 Cardiovascular devices	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT233 Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT2406 Implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT2407 Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT258 Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT2727 Active implant devices/incinerates	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT2750 Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT2866 Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT2985 Active	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT3001 Implantable metal	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT3002 Implantable synthetic polymer	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT3006 Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT3007 Implantable ceramic	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT314 Electrically powered	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT321 Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT449 Generators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT981 Single use	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
					CT983 Surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	18/12/2018	
4060	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010 Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147 Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150 Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141 Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145 Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233 Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406 Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407 Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258 Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263 Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726 Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727 Active implant devices/incinerates	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750 Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866 Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985 Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001 Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002 Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

4061	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2966	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4062	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
4063	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4064	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4065	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4066	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

4067	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4068	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
4073	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT233	Surgical	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT2406	Implantable	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT2985	Active	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT981	Single use	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A072201	High Impedance	11/12/2018	
4074	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
4075	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4076	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					CT233	Surgical	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	

					C12406	Implantable	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C12407	Active implantable	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C1258	Implantable defibrillators	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C12727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C12750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C12866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C12985	Active	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C13001	Implantable metal	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C13002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C13006	Implantable inorganic material	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C13007	Implantable ceramic	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C1314	Electrically powered	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C1449	Generators and associated devices	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					C1981	Single use	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection	13/12/2018	
4077	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	C11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C11151	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2019	
4078	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	C11010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C11147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C11150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C1145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C12406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C12407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C1258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C12727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C12750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C12866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C12985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C13001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C13002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C13006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C13007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C1314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C1449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					C1981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/10/2019	
4079	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	C11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2018	

4085	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
4086	2018	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4087	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

4088	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4089	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
4090	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	

					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2019	
4091	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/12/2018	
4092	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2728	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4093	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

4094	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					4095	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070101	Failure to Capture		
					4096	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
										CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
										CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201						High Impedance							
4097	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator						CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019	
										CT1150	Defibrillators	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019	
										CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019	
										CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019	
										CT233	Surgical	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT2407	Active implantable	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT2985	Active	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT314	Electrically powered	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT981	Single use	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	08/01/2019						
					4098	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
										CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
										CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
										CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
										CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
CT2406	Implantable	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT2985	Active	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT314	Electrically powered	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT981	Single use	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							
CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery							

4099	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					4100	2019	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910						Undersensing							
4101	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator						CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019	
										CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019	
										CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019	
										CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019	
										CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019	
										CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019	
										CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019	
										CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2019						
					4102	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/01/2019	

					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4103	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4104	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT1145	Cardiovascular devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	05/11/2019	
4105	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

4106	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4107	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/01/2019	
4108	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019	
4109	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
4110	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	

					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT440	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/01/2019	
4111	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT440	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	
4112	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090201	Device Displays Incorrect Message		
4113	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT440	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4114	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
4115	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							P26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019

CT141	Electrodes/Leads and associated devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT1233	Surgical	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT12407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT1258	Implantable defibrillators	F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT12727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT12750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT2865	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT12985	Active	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT3001	Implantable metal	F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT314	Electrically powered	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT321	Long-term surgical invasive	F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
CT981	Single use	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019

							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	09/01/2019	09/01/2019
4116	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads end associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4117	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
4118	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019	

					CT1150	Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT233	Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT2406	Implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT981	Single use	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	21/01/2019		
4119	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
4120	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
4121	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			

					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4122	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
4123	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4124	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4125	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4126	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		

4127	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070603	Failure to Charge	21/01/2019	
4128	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4129	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection		
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection		
4130	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4131	2019	All other reportable incidents	47940	Triple-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	

					CT141	Electrodes/leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2408	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT3008	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
4132	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2408	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4133	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT2408	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
4134	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2408	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4135	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
4136	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4137	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4138	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4139	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2504	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
4140	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4141	2019	Unanticipated serious deterioration in state of health	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT1150	Defibrillators	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT233	Surgical	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT2406	Implantable	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT2407	Active implantable	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT2985	Active	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT3001	Implantable metal	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT314	Electrically powered	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT449	Generators and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT981	Single use	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
					CT983	Surgical invasive	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	23/01/2019	
4142	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070909	Oversensing	02/01/2019	
4143	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	02/01/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge		

					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT233	Surgical	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT2985	Active	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT981	Single use	F1905	Device Revision or Replacement	A070603	Failure to Charge		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070603	Failure to Charge		
4144	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4145	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
4146	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4147	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
4148	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	

4149	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2019	
					CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A071102	Failure to Interrogate	17/01/2019	
4150	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2019	
4151	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
4152	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4153	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/01/2019	
4154	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
4155	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/02/2019	
4156	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4160	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4161	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4162	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4163	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4164	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4165	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		

4166	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4167	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F1905	Device Revision or Replacement	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT2727	Active implant devices/ancillaries	F21	Unexpected Deterioration	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F21	Unexpected Deterioration	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	F21	Unexpected Deterioration	A070910	Undersensing		
					CT2985	Active	F21	Unexpected Deterioration	A070910	Undersensing		
					CT3001	Implantable metal	F21	Unexpected Deterioration	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	F21	Unexpected Deterioration	A070910	Undersensing		
					CT3006	Implantable inorganic material	F21	Unexpected Deterioration	A070910	Undersensing		
					CT3007	Implantable ceramic	F21	Unexpected Deterioration	A070910	Undersensing		
					CT314	Electrically powered	F21	Unexpected Deterioration	A070910	Undersensing		
					CT321	Long-term surgical invasive	F21	Unexpected Deterioration	A070910	Undersensing		
					CT449	Generators and associated devices	F21	Unexpected Deterioration	A070910	Undersensing		
					CT981	Single use	F21	Unexpected Deterioration	A070910	Undersensing		
					CT983	Surgical invasive	F21	Unexpected Deterioration	A070910	Undersensing		
4173	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
4174	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
4175	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2019	
4176	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4177	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4178	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		

					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
4179	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/02/2019	
4180	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		

		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT141	Electrodes,Leads and associated devices	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensimg		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

					F26	No Health Consequences or Impact	A071302 A070909 A071302 A070909 A071302	Inappropriate/inadequate Shock/Stimulation Oversensing Inappropriate/inadequate Shock/Stimulation Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation				
4185	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	21/01/2020	21/01/2020
4186	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/inciliaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4187	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/inciliaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4188	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		

						CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2019	06/12/2019
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2019	06/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2019	06/12/2019
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/12/2019	06/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/12/2019	06/12/2019
4190	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT3134	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
					CT983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	06/01/2021	06/01/2021
								F26	No Health Consequences or Impact	A070909	Oversensing	06/01/2021	06/01/2021
4191	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3134	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4192	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4193	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
4194	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT258	implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT3001	implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT3002	implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT3006	implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
									A090201	Device Displays Incorrect Message	03/01/2020	03/01/2020
4195	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/02/2019	
4196	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		

4197	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
					CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT1150	Defibrillators	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT1141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT233	Surgical	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT2406	Implantable	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT2407	Active implantable	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT2985	Active	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT3001	Implantable metal	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT3007	Implantable ceramic	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT314	Electrically powered	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT321	Long-term surgical invasive	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
					CT449	Generators and associated devices	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019						
							F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019						
CT981	Single use	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019											
		F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019											
CT983	Surgical invasive	E1906	Unspecified Infection	A010102	Device Appears to Trigger Rejection	25/01/2019											
		F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	25/01/2019											
4198	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					4199	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
										CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
										CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		

					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3134	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT321	Long term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
4200	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT3134	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/12/2019	09/12/2019
4201	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
									A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
									A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
									A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
									A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
									A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
									A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
									A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
									A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
									A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
									A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020
							F19	Surgical Intervention	A090201	Device Displays Incorrect Message	09/01/2020	09/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/01/2020	09/01/2020

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4203	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	15/02/2019											
					CT440	Generators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	15/02/2019											
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	15/02/2019											
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					4204	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery							
CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT440	Generators and associated devices	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT981	Single use	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT233	Surgical	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT2406	Implantable	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT2985	Active	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery												
4205	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT440	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery												
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT233	Surgical	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT2406	Implantable	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT2985	Active	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
4206	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT440	Generators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT981	Single use	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070909	Oversensing	11/12/2019	11/12/2019										
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/11/2019	20/11/2019										
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/11/2019	20/11/2019										
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/11/2019	20/11/2019										
					4207	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/11/2019	20/11/2019					
												F1901	Additional Surgery	A071102	Failure to Interrogate	20/11/2019	20/11/2019					
														A070504	Premature Discharge of Battery	20/11/2019	20/11/2019					
														A071102	Failure to Interrogate	20/11/2019	20/11/2019					
										4208	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
															CT1150	Defibrillators	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
															CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
															CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
															CT233	Surgical	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
															CT2406	Implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
															CT2407	Active implantable	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A07											Electrical /Electronic Property Problem	14/02/2019						
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A07											Electrical /Electronic Property Problem	14/02/2019						
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A07											Electrical /Electronic Property Problem	14/02/2019						
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A07											Electrical /Electronic Property Problem	14/02/2019						
CT2985	Active	F1905	Device Revision or Replacement	A07											Electrical /Electronic Property Problem	14/02/2019						
CT3001	Implantable metal	F1905	Device Revision or Replacement	A07											Electrical /Electronic Property Problem	14/02/2019						

					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	14/02/2019	
4209	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/12/2019	20/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/12/2019	20/12/2019
4210	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2019	24/09/2019
4211	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2019	26/11/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2019	26/11/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2019	26/11/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2019	26/11/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2019	26/11/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2019	26/11/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2019	26/11/2019

					CT145	Cardiovascular devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT233	Surgical	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT2406	Implantable	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT2407	Active implantable	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT258	implantable defibrillators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT263	Cardiographs and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT2726	Physiological monitoring/measuring devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT2727	Active implant devices/ancillaries	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT2866	Implantable cardiac electrical stimulators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT2985	Active	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT3001	implantable metal	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT3002	Implantable synthetic polymer	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT3006	Implantable inorganic material	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT3007	Implantable ceramic	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT314	Electrically powered	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT321	Long-term surgical invasive	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT449	Generators and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT981	Single use	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
					CT983	Surgical invasive	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	26/11/2019 26/11/2019	26/11/2019 26/11/2019
4212	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F10 F23	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure Unexpected Medical Intervention	A071301 A071301 A071301	Failure to Deliver Shock/Stimulation Failure to Deliver Shock/Stimulation Failure to Deliver Shock/Stimulation	26/11/2019 [REDACTED] [REDACTED]	26/11/2019 [REDACTED] [REDACTED]
4213	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT1147	Defibrillators and associated devices	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT1150	Defibrillators	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT141	Electrodes/Leads and associated devices	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT145	Cardiovascular devices	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT233	Surgical	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT2406	Implantable	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT2407	Active implantable	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT258	Implantable defibrillators	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT263	Cardiographs and associated devices	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT2726	Physiological monitoring/measuring devices	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT2727	Active implant devices/ancillaries	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT2866	Implantable cardiac electrical stimulators	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
					CT2985	Active	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070603 A070603	Failure to Charge Failure to Charge	09/12/2019 09/12/2019	09/12/2019 09/12/2019

						CT3001	Implantable metal	F1905 E2403 F1901 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019 09/12/2019
						CT3002	Implantable synthetic polymer	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
						CT3006	Implantable inorganic material	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
						CT3007	Implantable ceramic	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
						CT314	Electrically powered	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
						CT321	Long-term surgical invasive	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
						CT449	Generators and associated devices	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
						CT981	Single use	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
						CT983	Surgical invasive	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070603 A070603 A070603	Failure to Charge Failure to Charge Failure to Charge	09/12/2019 09/12/2019 09/12/2019	09/12/2019 09/12/2019 09/12/2019
4214	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2401 E2403 F08 F1901 F1903	Insufficient Information No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Additional Surgery Device Explanation	A070504 A070504 A070504 A070504 A070504	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	
					CT1150	Defibrillators	E2401 E2403 F08 F1901 F1903	Insufficient Information No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Additional Surgery Device Explanation	A070504 A070504 A070504 A070504 A070504	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	
					CT141	Electrodes/Leads and associated devices	E2401 E2403 F08 F1901 F1903	Insufficient Information No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Additional Surgery Device Explanation	A070504 A070504 A070504 A070504 A070504	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	
					CT145	Cardiovascular devices	E2401 E2403 F08 F1901 F1903	Insufficient Information No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Additional Surgery Device Explanation	A070504 A070504 A070504 A070504 A070504	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	
					CT233	Surgical	E2401 E2403 F08 F1901 F1903	Insufficient Information No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Additional Surgery Device Explanation	A070504 A070504 A070504 A070504 A070504	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	
					CT2406	Implantable	E2401 E2403 F08 F1901 F1903	Insufficient Information No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Additional Surgery Device Explanation	A070504 A070504 A070504 A070504 A070504	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	01/04/2019 01/04/2019 01/04/2019 01/04/2019 01/04/2019	
					CT2407	Active implantable	E2401	Insufficient Information	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019	

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					CT3007	Implantable ceramic	E2401	Insufficient Information	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/04/2019	01/04/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
					CT314	Electrically powered	E2401	Insufficient Information	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/04/2019	01/04/2019
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/04/2019	01/04/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/04/2019	01/04/2019
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
					CT449	Generators and associated devices	E2401	Insufficient Information	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/04/2019	01/04/2019
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
					CT981	Single use	E2401	Insufficient Information	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/04/2019	01/04/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
					CT983	Surgical invasive	E2401	Insufficient Information	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/04/2019	01/04/2019
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/04/2019	01/04/2019
4215	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		

					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
4216	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
4217	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/02/2021	10/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
									A070909	Oversensing	10/02/2021	10/02/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021

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									A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/02/2021	10/02/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	10/02/2021	10/02/2021	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021
								A070909	Oversensing	10/02/2021	10/02/2021	
						F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021	
								A070909	Oversensing	10/02/2021	10/02/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021	
								A070909	Oversensing	10/02/2021	10/02/2021	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/02/2021	10/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/02/2021	10/02/2021	
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	10/02/2021	10/02/2021	
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/02/2021	10/02/2021	
4218	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/11/2019	29/11/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	29/11/2019	29/11/2019
4219	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4220	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019

								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
					CT983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/12/2019	11/12/2019	11/12/2019
4221	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
					CT983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/12/2019	27/12/2019	27/12/2019
4222	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			

					CT321	Long-term surgical invasive	F1905 Device Revision or Replacement A070504 E2403 No Clinical Signs, Symptoms or Conditions A070504 F1901 Additional Surgery A070504 F1905 Device Revision or Replacement A070504	Premature Discharge of Battery A070504 Premature Discharge of Battery A070504 Premature Discharge of Battery A070504 Premature Discharge of Battery A070504	26/11/2019 26/11/2019 26/11/2019 26/11/2019	26/11/2019 26/11/2019 26/11/2019 26/11/2019
					CT449	Generators and associated devices	E2403 No Clinical Signs, Symptoms or Conditions A070504 F1901 Additional Surgery A070504 F1905 Device Revision or Replacement A070504	Premature Discharge of Battery A070504 Premature Discharge of Battery A070504 Premature Discharge of Battery A070504	26/11/2019 26/11/2019 26/11/2019	26/11/2019 26/11/2019 26/11/2019
					CT981	Single use	E2403 No Clinical Signs, Symptoms or Conditions A070504 F1901 Additional Surgery A070504 F1905 Device Revision or Replacement A070504	Premature Discharge of Battery A070504 Premature Discharge of Battery A070504 Premature Discharge of Battery A070504	26/11/2019 26/11/2019 26/11/2019	26/11/2019 26/11/2019 26/11/2019
					CT983	Surgical invasive	E2403 No Clinical Signs, Symptoms or Conditions A070504 F1901 Additional Surgery A070504 F1905 Device Revision or Replacement A070504	Premature Discharge of Battery A070504 Premature Discharge of Battery A070504 Premature Discharge of Battery A070504	26/11/2019 26/11/2019 26/11/2019	26/11/2019 26/11/2019 26/11/2019
4226	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A070909 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A071302 inappropriate/inadequate Shock/Stimulation A071302		
					CT1147	Defibrillators and associated devices	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A070909 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT1150	Defibrillators	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT141	Electrodes/Leads and associated devices	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT145	Cardiovascular devices	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT233	Surgical	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT2406	Implantable	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT2407	Active implantable	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT258	Implantable defibrillators	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT263	Cardiographs and associated devices	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT2726	Physiological monitoring/measuring devices	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT2727	Active implant devices/ancillaries	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302 F26 No Health Consequences or Impact A070909	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909 inappropriate/inadequate Shock/Stimulation A071302		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060102 Atrial Fibrillation A070909 E2403 No Clinical Signs, Symptoms or Conditions A071302	inappropriate/inadequate Shock/Stimulation A071302 Oversensing A070909		

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/01/2020	03/01/2020
4228	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/02/2019	
4229	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4230	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4235	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4236	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	22/02/2021	22/02/2021
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F1905	Device Revision or Replacement	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	22/02/2021	22/02/2021
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F1905	Device Revision or Replacement	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	22/02/2021	22/02/2021
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F1905	Device Revision or Replacement	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	22/02/2021	22/02/2021
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F1905	Device Revision or Replacement	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	22/02/2021	22/02/2021
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
						F1905	Device Revision or Replacement	A070909	Oversensing	22/02/2021	22/02/2021	
									A0712	Pacing Problem	22/02/2021	22/02/2021
									A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	22/02/2021	22/02/2021
									A0712	Pacing Problem	22/02/2021	22/02/2021

				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
				A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
				A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
				A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
				A070909	Overensing	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
				A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
				A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
				A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
				A070909	Overensing	22/02/2021	22/02/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
		F1905	Device Revision or Replacement	A070909	Overensing	22/02/2021	22/02/2021
				A0712	Pacing Problem	22/02/2021	22/02/2021
				A090801	Signal Artifact/Noise	22/02/2021	22/02/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	22/02/2021	22/02/2021

					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4240	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
4241	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4242	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
4243	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/01/2020	08/01/2020
							F1001	Additional Surgery	A070504	Premature Discharge of Battery	08/01/2020	08/01/2020
							F1005	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/01/2020	08/01/2020
4244	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
4245	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert	20/01/2020	20/01/2020
							F26	No Health Consequences or Impact	A150206	Difficult to Insert	20/01/2020	20/01/2020
4246	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

4247	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070908	Failure to Sense		
4248	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
4249	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/12/2019	31/12/2019

[illegible]

[illegible]

[illegible]

					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
4256	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4257	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A110401	Operating System Becomes Nonfunctional	06/02/2019	
4258	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4259	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/02/2019	
4260	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4261	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2019	
4262	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4263	2020	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A0701	Capturing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
						F02	Death		A0701	Capturing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0701	Capturing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
4264	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/01/2020	06/01/2020
4265	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2020	10/01/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/01/2020	21/01/2020
4267	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/03/2019	20/03/2019
4268	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
4269	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT1233	Surgical	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT2985	Active	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT981	Single use	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504 A090201	Premature Discharge of Battery Device Displays Incorrect Message	16/01/2020	16/01/2020
4270	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4273	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2019	23/12/2019
4274	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	06/12/2019	06/12/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Pacing Problem	06/12/2019	06/12/2019
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	06/12/2019	06/12/2019
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem	06/12/2019	06/12/2019
									A0712	Pacing Problem	06/12/2019	06/12/2019
									A09	Output Problem	06/12/2019	06/12/2019
4275	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070602	Delayed Charge Time		
4276	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/01/2020	22/01/2020
4277	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	01/03/2019	01/03/2019
4278	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4279	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
4280	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/03/2019	
4281	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		

					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
4282	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4283	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	02/10/2018	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2018	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	02/10/2018	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2018	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	02/10/2018	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2018	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	02/10/2018	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2018	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	02/10/2018	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2018	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	02/10/2018	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2018	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	02/10/2018	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2018	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	02/10/2018	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2018	

					CT3007	implantable ceramic	E2403	No Health Consequences or Impact	A072201	High Impedance		
						Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Long-term surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Generators and associated devices	E2403	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Single use	E2403	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Surgical invasive	E2403	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4287	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographic and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/leads/catheters	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
4288	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT233	Surgical	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2406	Implantable	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2407	Active implantable	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2727	Active implant devices/leads/catheters	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2985	Active	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT981	Single use	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
4289	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT233	Surgical	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2406	Implantable	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2407	Active implantable	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2727	Active implant devices/leads/catheters	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT2985	Active	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT981	Single use	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A090201	Device Displays Incorrect Message	07/01/2020	07/01/2020
4290	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
4291	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4292	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
4293	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
4294	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		

					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
4295	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4296	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
4297	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT3114	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/02/2019	
4298	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT3114	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/01/2020	17/01/2020
4299	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	

						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2019	
4300	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation								
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation									
	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation								
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation									
	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation								
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation									
	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation								
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation									
	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation								
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation									

					CT981	Single use	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
4301	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A071302 A072201	Inappropriate/Inadequate Shock/Stimulation High Impedance	01/05/2019	01/05/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	01/05/2019	01/05/2019
4302	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4303	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
4304	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	20/03/2019	
4305	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4306	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT1147	Defibrillators and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT1150	Defibrillators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT141	Electrodes/Leads and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT145	Cardiovascular devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT233	Surgical	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT2406	Implantable	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT2407	Active implantable	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT258	Implantable defibrillators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT263	Cardiographs and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT2726	Physiological monitoring/measuring devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT2727	Active implant devices/ancillaries	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT2866	Implantable cardiac electrical stimulators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT2985	Active	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT3001	Implantable metal	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2020	28/01/2020
4307	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4308	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4309	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4310	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
4311	2020	Death	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT1150	Defibrillators	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT141	Electrodes/Leads and associated devices	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT145	Cardiovascular devices	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT233	Surgical	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT2406	Implantable	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT2407	Active implantable	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT258	Implantable defibrillators	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT2727	Active implant devices/ancillaries	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT2866	Implantable cardiac electrical stimulators	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT2985	Active	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020

					CT3001	Implantable metal	E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT3002	Implantable synthetic polymer	F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT3006	Implantable inorganic material	F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT3007	Implantable ceramic	F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT314	Electrically powered	F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT321	Long-term surgical invasive	F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT449	Generators and associated devices	F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT981	Single use	F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
					CT983	Surgical invasive	F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							E0611	Heart Failure/Congestive Heart Failure	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F02	Death	A24	No Apparent Device Problem	19/01/2020	19/01/2020
							F21	Unexpected Deterioration	A24	No Apparent Device Problem	19/01/2020	19/01/2020
4312	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4313	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

					associated devices	F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4314	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
4315	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

4316	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT981	Single use	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2407	Active implantable	F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT3001	Implantable metal	F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT3007	Implantable ceramic	F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT449	Generators and associated devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
4317	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	02/04/2019	
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/04/2019	
4318	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	

					CT1321	Long-term surgical invasive	F1905	Device Revision or Replacement	A07098	Charging Problem	29/03/2019	
					CT1449	Generators and associated devices	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0706	Charging Problem	29/03/2019	
4319	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT1141	Electrodes/leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT1145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT1233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT2408	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT1258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT1263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT12726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT12727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT12750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT3134	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT1449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/04/2019	
4320	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2408	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3134	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4321	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT2408	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1901	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
						Additional Surgery	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2020	03/02/2020

4323	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/01/2020	30/01/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/01/2020	30/01/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/01/2020	30/01/2020
4324	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	24/01/2020	24/01/2020
									A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020

							F1905	Device Revision or Replacement	A070909	Oversensing	24/01/2020	24/01/2020
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A070909	Oversensing	24/01/2020	24/01/2020
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem	24/01/2020	24/01/2020
							F1905	Device Revision or Replacement	A070909	Oversensing	24/01/2020	24/01/2020
									A0712	Pacing Problem	24/01/2020	24/01/2020
4325	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
4326	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/02/2020	12/02/2020
4327	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2019	
4328	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
4329	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		

					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722 A072201 A090801	Impedance Problem High Impedance Signal Artifact/Noise		
4330	2020	All other reportable incidents	07265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/01/2020	27/01/2020
4331	2020	All other reportable incidents	07265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020

CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2886	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
4333	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
4334	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4335	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4336	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4337	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		

					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT2886	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/04/2019	
4341	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4342	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT2886	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	04/04/2019	
4343	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019

					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT440	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		26/04/2019
4344	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4345	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	10/04/2019	
4346	2019	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A26	Insufficient Device Problem Information		
4347	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
									A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
									A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019

4348	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2019	12/12/2019
							A090201	Device Displays Incorrect Message	12/12/2019	12/12/2019		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT1145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
		A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020							
4349	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2020	02/01/2020
							A090201	Device Displays Incorrect Message	02/01/2020	02/01/2020		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
		F26	No Health Consequences or Impact	A072202	Low Impedance							
4350	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A072202	Low Impedance		

					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
4351	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
4352	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	04/02/2020 04/02/2020 04/02/2020	04/02/2020 04/02/2020 04/02/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602	Premature Discharge of Battery Delayed Charge Time	04/02/2020 04/02/2020	04/02/2020 04/02/2020

					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4358	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4359	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2114	Perforation	A0101	Patient-Device Incompatibility	29/03/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0101	Patient-Device Incompatibility	29/03/2019	
					CT1150	Defibrillators	E2114	Perforation	A0101	Patient-Device Incompatibility	29/03/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0101	Patient-Device Incompatibility	29/03/2019	
					CT145	Cardiovascular devices	E2114	Perforation	A0101	Patient-Device Incompatibility	29/03/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A0101	Patient-Device Incompatibility	29/03/2019	
					CT2406	Implantable	E2114	Perforation	A0101	Patient-Device Incompatibility	29/03/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0101	Patient-Device Incompatibility	29/03/2019	
					CT258	Implantable defibrillators	E2114	Perforation	A0101	Patient-Device Incompatibility	29/03/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0101	Patient-Device Incompatibility	29/03/2019	
					CT2726	Physiological monitoring/measuring devices	E2114	Perforation	A0101	Patient-Device Incompatibility	29/03/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0101	Patient-Device Incompatibility	29/03/2019	

					CT3006	Implantable inorganic material	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/02/2020 13/02/2020 13/02/2020	13/02/2020 13/02/2020 13/02/2020
					CT3007	Implantable ceramic	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/02/2020 13/02/2020 13/02/2020	13/02/2020 13/02/2020 13/02/2020
					CT314	Electrically powered	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/02/2020 13/02/2020 13/02/2020	13/02/2020 13/02/2020 13/02/2020
					CT321	Long-term surgical invasive	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/02/2020 13/02/2020 13/02/2020	13/02/2020 13/02/2020 13/02/2020
					CT449	Generators and associated devices	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/02/2020 13/02/2020 13/02/2020	13/02/2020 13/02/2020 13/02/2020
					CT981	Single use	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/02/2020 13/02/2020 13/02/2020	13/02/2020 13/02/2020 13/02/2020
					CT983	Surgical invasive	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/02/2020 13/02/2020 13/02/2020	13/02/2020 13/02/2020 13/02/2020
4365	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
4366	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
4367	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070604 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/02/2020 15/02/2020 15/02/2020	15/02/2020 15/02/2020 15/02/2020
					CT1150	Defibrillators	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/02/2020 15/02/2020 15/02/2020	15/02/2020 15/02/2020 15/02/2020
					CT141	Electrodes/Leads and associated devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/02/2020 15/02/2020 15/02/2020	15/02/2020 15/02/2020 15/02/2020
					CT145	Cardiovascular devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/02/2020 15/02/2020 15/02/2020	15/02/2020 15/02/2020 15/02/2020
					CT233	Surgical	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/02/2020 15/02/2020 15/02/2020	15/02/2020 15/02/2020 15/02/2020
					CT2406	Implantable	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/02/2020 15/02/2020 15/02/2020	15/02/2020 15/02/2020 15/02/2020
					CT2407	Active implantable	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/02/2020 15/02/2020 15/02/2020	15/02/2020 15/02/2020 15/02/2020
					CT258	Implantable defibrillators	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	15/02/2020 15/02/2020	15/02/2020 15/02/2020

					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2020	15/02/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/03/2020	01/03/2020
4369	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E060109	Tachycardia	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4370	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4371	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071207	Pacing Inadequately		
4372	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2986	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4373	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2986	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4374	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2986	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4375	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1070	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2986	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		

4376	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4377	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4378	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		

					CT1150	Defibrillators	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT141	Electrodes/Leads and associated devices	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT145	Cardiovascular devices	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT233	Surgical	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT2406	Implantable	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT2407	Active implantable	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT258	Implantable defibrillators	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT2727	Active implant devices/ancillaries	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT2866	Implantable cardiac electrical stimulators	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT2985	Active	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT3001	Implantable metal	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT3002	Implantable synthetic polymer	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT3006	Implantable inorganic material	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT3007	Implantable ceramic	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT314	Electrically powered	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT321	Long-term surgical invasive	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT449	Generators and associated devices	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT981	Single use	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
					CT983	Surgical invasive	F105	Device Revision or Replacement	A	Annex A	09/04/2019	
							F105	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A	09/04/2019	
							F105	Device Revision or Replacement	A	Annex A	09/04/2019	
4382	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT1150	Defibrillators	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT141	Electrodes/Leads and associated devices	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT145	Cardiovascular devices	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT233	Surgical	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2406	Implantable	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2407	Active implantable	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT258	Implantable defibrillators	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2727	Active implant devices/ancillaries	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2866	Implantable cardiac electrical stimulators	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT2985	Active	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT3001	Implantable metal	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT3002	Implantable synthetic polymer	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT3006	Implantable inorganic material	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT3007	Implantable ceramic	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT314	Electrically powered	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT321	Long-term surgical invasive	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT449	Generators and associated devices	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT981	Single use	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
					CT983	Surgical invasive	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
							F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
4383	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	F105	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2020	07/02/2020
4384	2019	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1146	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT286	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
4388	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT12408	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/02/2021	24/02/2021

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				Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT145	Cardiovascular devices	E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/anillaries	F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact		A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
4392	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
4393	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		

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					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
4394	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E060109	Tachycardia	A070910	Undersensing		
					CT1150	Defibrillators	E060109	Tachycardia	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A070910	Undersensing		
					CT145	Cardiovascular devices	E060109	Tachycardia	A070910	Undersensing		
					CT233	Surgical	E060109	Tachycardia	A070910	Undersensing		
					CT2406	Implantable	E060109	Tachycardia	A070910	Undersensing		
					CT2407	Active implantable	E060109	Tachycardia	A070910	Undersensing		
					CT258	Implantable defibrillators	E060109	Tachycardia	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E060109	Tachycardia	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E060109	Tachycardia	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A070910	Undersensing		
					CT2966	Implantable cardiac electrical stimulators	E060109	Tachycardia	A070910	Undersensing		
					CT2985	Active	E060109	Tachycardia	A070910	Undersensing		
					CT3001	Implantable metal	E060109	Tachycardia	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E060109	Tachycardia	A070910	Undersensing		
					CT3006	Implantable inorganic material	E060109	Tachycardia	A070910	Undersensing		
					CT3007	Implantable ceramic	E060109	Tachycardia	A070910	Undersensing		
					CT314	Electrically powered	E060109	Tachycardia	A070910	Undersensing		
					CT321	Long-term surgical invasive	E060109	Tachycardia	A070910	Undersensing		
					CT449	Generators and associated devices	E060109	Tachycardia	A070910	Undersensing		
					CT981	Single use	E060109	Tachycardia	A070910	Undersensing		
					CT983	Surgical invasive	E060109	Tachycardia	A070910	Undersensing		
4395	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020

					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation	07/02/2020	07/02/2020
4400	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
					CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
					CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
4401	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4402	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/03/2020	24/03/2020

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					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2104	Electric Shock	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem		
4404	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT983	Surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4405	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
4411	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
4412	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4413	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

4414	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
4415	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2019	
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4416	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4416	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
					CT145	Cardiovascular devices	F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
					CT2406	Implantable	F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019

					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance	15/05/2019	15/05/2019
							F26	No Health Consequences or Impact	A072202	Low Impedance	15/05/2019	15/05/2019
4417	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2019	
4418	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2019	
4419	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4420	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/05/2019	
4421	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/04/2019	
4422	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020

							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	10/03/2020	10/03/2020
4423	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
4424	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
4425	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT1147	Defibrillators and associated devices	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT1150	Defibrillators	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT141	Electrodes/Leads and associated devices	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT145	Cardiovascular devices	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT233	Surgical	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT2406	Implantable	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT2407	Active implantable	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT258	Implantable defibrillators	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT263	Cardiographs and associated devices	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT2726	Physiological monitoring/measuring devices	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT2727	Active implant devices/ancillaries	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT2866	Implantable cardiac electrical stimulators	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT2985	Active	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT3001	Implantable metal	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT3002	Implantable synthetic polymer	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT3006	Implantable inorganic material	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT3007	Implantable ceramic	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT314	Electrically powered	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT321	Long-term surgical invasive	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT449	Generators and associated devices	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT981	Single use	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
					CT983	Surgical invasive	F21	Unexpected Deterioration	A070909	Oversensing	28/04/2019	
4426	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4427	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/03/2020	11/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/03/2020	11/03/2020
4428	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/03/2020	02/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	02/03/2020	02/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/03/2020	02/03/2020
4429	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	13/03/2020	13/03/2020

						CT1263	Cardiographs and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT12726	Physiological monitoring/measuring devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT12727	Active implant devices/ancillaries	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT12750	Implantable cardiac electrical stimulators and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT12866	Implantable cardiac electrical stimulators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT12985	Active	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT13001	implantable metal	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT13002	Implantable synthetic polymer	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT13008	Implantable inorganic material	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT13007	Implantable ceramic	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT1314	Electrically powered	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT1321	Long-term surgical invasive	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT1449	Generators and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT1981	Single use	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
						CT1983	Surgical invasive	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/03/2020 13/03/2020	13/03/2020 13/03/2020
4430	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1147	Defibrillators and associated devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT1150	Defibrillators	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT1141	Electrodes/Leads and associated devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT1145	Cardiovascular devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT1233	Surgical	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT12406	implantable	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT12407	Active implantable	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT1258	implantable defibrillators	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT12727	Active implant devices/ancillaries	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	
						CT12750	Implantable cardiac electrical stimulators and associated devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A0712 A071302 A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation	 	

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/03/2020	20/03/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/03/2020	20/03/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/03/2020	20/03/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/03/2020	20/03/2020
4432	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E1906	Unspecified Infection	A24	No Apparent Device Problem		
4433	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	28/02/2021	28/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	28/02/2021	28/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	28/02/2021	28/02/2021
							F1905	Device Revision or Replacement	A072201	High Impedance	28/02/2021	28/02/2021
									A070909	Oversensing	28/02/2021	28/02/2021
									A072201	High Impedance	28/02/2021	28/02/2021
4434	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A150205	Difficult to Advance		
4435	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4436	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT1150	Defibrillators	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT145	Cardiovascular devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT2406	Implantable	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT258	Implantable defibrillators	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT2985	Active	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT3002	Implantable synthetic polymer	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT3007	Implantable ceramic	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020

					CT314	Electrically powered	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT321	Long-term surgical invasive	F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/03/2020	14/04/2020
4437	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4438	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020

					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/03/2020	17/03/2020
4439	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2728	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4440	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	27/03/2020	27/03/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2020	27/03/2020
									A071102	Failure to Interrogate	27/03/2020	27/03/2020

						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/05/2020	01/05/2020
						CT321	Long-term surgical invasive	F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/05/2020	01/05/2020
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/05/2020	01/05/2020
						CT981	Single use	F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/05/2020	01/05/2020
						CT983	Surgical invasive	F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/05/2020	01/05/2020
4445	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/05/2020	01/05/2020
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4446	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A072202	Low Impedance		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A072202	Low Impedance		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A072202	Low Impedance		
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A072202	Low Impedance		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
						CT981	Single use	F26	No Health Consequences or Impact	A072202	Low Impedance		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
4447	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A072202	Low Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
								F08	Hospitalization or Prolonged Hospitalization	A1601	Device Alarm System	11/03/2020	11/03/2020
								F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
								F19	Surgical Intervention	A1601	Device Alarm System	11/03/2020	11/03/2020
										A0705	Battery Problem	11/03/2020	11/03/2020
										A1601	Device Alarm System	11/03/2020	11/03/2020

CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System	11/03/2020	11/03/2020
				A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
CT1150	Defibrillators			A1601	Device Alarm System	11/03/2020	11/03/2020
		F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
CT1141	Electrodes/Leads and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
CT1145	Cardiovascular devices			A1601	Device Alarm System	11/03/2020	11/03/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
CT233	Surgical	F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/03/2020	11/03/2020
CT2408	Implantable			A1601	Device Alarm System	11/03/2020	11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
CT2406	Implantable defibrillators			A1601	Device Alarm System	11/03/2020	11/03/2020
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
CT263	Cardiographs and associated devices	F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
				A1601	Device Alarm System	11/03/2020	11/03/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020

		F1905	Device Revision or Replacement	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Device Alarm System	11/03/2020	11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Battery Problem Device Alarm System	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F19	Surgical Intervention	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F1905	Device Revision or Replacement	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Battery Problem Device Alarm System	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A0705 A1601	Battery Problem Device Alarm System	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F19	Surgical Intervention	A0705 A1601	Battery Problem Device Alarm System	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F1905	Device Revision or Replacement	A0705 A1601	Battery Problem Device Alarm System	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F19	Surgical Intervention	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F1905	Device Revision or Replacement	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Battery Problem Device Alarm System	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F19	Surgical Intervention	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F1905	Device Revision or Replacement	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F19	Surgical Intervention	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F1905	Device Revision or Replacement	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F19	Surgical Intervention	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F1905	Device Revision or Replacement	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F19	Surgical Intervention	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F1905	Device Revision or Replacement	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F19	Surgical Intervention	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F1905	Device Revision or Replacement	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F08	Hospitalization or Prolonged Hospitalization	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020
		F12	Serious Injury/ Illness/ Impairment	A1601 A0705	Device Alarm System Battery Problem	11/03/2020 11/03/2020	11/03/2020 11/03/2020

						F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
						F1905	Device Revision or Replacement	A1601	Device Alarm System	11/03/2020	11/03/2020
								A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
					CT314	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
						F08	Hospitalization or Prolonged Hospitalization	A1601	Device Alarm System	11/03/2020	11/03/2020
								A0705	Battery Problem	11/03/2020	11/03/2020
						F12	Serious Injury/ Illness/ Impairment	A1601	Device Alarm System	11/03/2020	11/03/2020
								A0705	Battery Problem	11/03/2020	11/03/2020
						F19	Surgical Intervention	A1601	Device Alarm System	11/03/2020	11/03/2020
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
					CT321	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
						F08	Hospitalization or Prolonged Hospitalization	A1601	Device Alarm System	11/03/2020	11/03/2020
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
						F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
						F1905	Device Revision or Replacement	A1601	Device Alarm System	11/03/2020	11/03/2020
								A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
					CT449	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
						F08	Hospitalization or Prolonged Hospitalization	A1601	Device Alarm System	11/03/2020	11/03/2020
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
						F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
						F1905	Device Revision or Replacement	A1601	Device Alarm System	11/03/2020	11/03/2020
								A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
					CT981	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
						F08	Hospitalization or Prolonged Hospitalization	A1601	Device Alarm System	11/03/2020	11/03/2020
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
						F19	Surgical Intervention	A1601	Device Alarm System	11/03/2020	11/03/2020
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
								A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
					CT983	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/03/2020	11/03/2020
						F08	Hospitalization or Prolonged Hospitalization	A1601	Device Alarm System	11/03/2020	11/03/2020
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	11/03/2020	11/03/2020
								A1601	Device Alarm System	11/03/2020	11/03/2020
						F19	Surgical Intervention	A0705	Battery Problem	11/03/2020	11/03/2020
						F1905	Device Revision or Replacement	A1601	Device Alarm System	11/03/2020	11/03/2020
								A0705	Battery Problem	11/03/2020	11/03/2020
4448	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A1601	Device Alarm System	11/03/2020
								A071205	Pacemaker Found in Back-Up Mode	20/05/2019	
4449	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	

					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4450	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT11403	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
4451	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/03/2020	09/07/2020

						associated devices	F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F1901	Additional Surgery	A070909	Oversensing		
							F1905	Device Revision or Replacement	A070909	Oversensing		
4454	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT2727	Active implant devices/implantables	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2019	
4455	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/05/2019	
4456	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	15/09/2022	15/09/2022
									A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A070909	Oversensing	15/09/2022	15/09/2022
									A072201	High Impedance	15/09/2022	15/09/2022

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	15/09/2022	15/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	15/09/2022	15/09/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	15/09/2022	15/09/2022
							F23	Unexpected Medical Intervention	A070909	Oversensing	15/09/2022	15/09/2022
4457	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A072201	High Impedance		
									A070909	Oversensing		

					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2019	
4459	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4460	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

4461	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12666	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F26	No Health Consequences or Impact	A070909	Oversensing							
CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A070909	Oversensing							
4462	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT12666	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/03/2020	30/03/2020

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4466	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/05/2019	
4467	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/03/2019	13/03/2019
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/03/2019	13/03/2019	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/03/2019	13/03/2019	

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					CT1272	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2020	01/04/2020
4469	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4470	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
4471	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4472	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT1147	Defibrillators and associated devices	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT1150	Defibrillators	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT141	Electrodes/Leads and associated devices	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT145	Cardiovascular devices	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT1233	Surgical	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT2406	Implantable	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT2407	Active implantable	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT258	Implantable defibrillators	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT263	Cardiographs and associated devices	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT2726	Physiological monitoring/measuring devices	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT2727	Active implant devices/ancillaries	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT2866	Implantable cardiac electrical stimulators	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT2985	Active	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					CT3001	Implantable metal	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
CT3002	Implantable synthetic polymer	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
CT3006	Implantable inorganic material	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
CT3007	Implantable ceramic	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
CT314	Electrically powered	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
CT321	Long-term surgical invasive	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021					

4473	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT449	Generators and associated devices	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021		
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021		
					CT981	Single use	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021		
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021		
					CT983	Surgical invasive	E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021		
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	07/02/2021	07/02/2021		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
4474	2019	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	
					F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019			
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019	

					CT314	Electrically powered	F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019		
					CT321	Long-term surgical invasive	F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019		
					CT449	Generators and associated devices	F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019		
					CT981	Single use	F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019		
					CT983	Surgical invasive	F21	Unexpected Deterioration	A072201	High Impedance	17/05/2019		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance	17/05/2019		
4475	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
4476	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
4477	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
4478	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4479	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		

							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT081	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
4480	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4481	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2020	09/04/2020

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					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	28/01/2018	28/01/2018
							F1905	Device Revision or Replacement	A072201	High Impedance	28/01/2018	28/01/2018
									A0203	Defective Device	28/01/2018	28/01/2018
							F24	Insufficient Health Impact Information	A072201	High Impedance	28/01/2018	28/01/2018
									A0203	Defective Device	28/01/2018	28/01/2018
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	28/01/2018	28/01/2018
							F1905	Device Revision or Replacement	A0203	Defective Device	28/01/2018	28/01/2018
									A072201	High Impedance	28/01/2018	28/01/2018
							F24	Insufficient Health Impact Information	A0203	Defective Device	28/01/2018	28/01/2018
									A072201	High Impedance	28/01/2018	28/01/2018
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	28/01/2018	28/01/2018
							F1905	Device Revision or Replacement	A072201	High Impedance	28/01/2018	28/01/2018
									A0203	Defective Device	28/01/2018	28/01/2018
							F24	Insufficient Health Impact Information	A072201	High Impedance	28/01/2018	28/01/2018
									A0203	Defective Device	28/01/2018	28/01/2018
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	28/01/2018	28/01/2018
							F1905	Device Revision or Replacement	A0203	Defective Device	28/01/2018	28/01/2018
									A072201	High Impedance	28/01/2018	28/01/2018
							F24	Insufficient Health Impact Information	A0203	Defective Device	28/01/2018	28/01/2018
									A072201	High Impedance	28/01/2018	28/01/2018
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	28/01/2018	28/01/2018
							F1905	Device Revision or Replacement	A072201	High Impedance	28/01/2018	28/01/2018
									A0203	Defective Device	28/01/2018	28/01/2018
							F24	Insufficient Health Impact Information	A072201	High Impedance	28/01/2018	28/01/2018
									A0203	Defective Device	28/01/2018	28/01/2018
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	28/01/2018	28/01/2018
							F1905	Device Revision or Replacement	A0203	Defective Device	28/01/2018	28/01/2018
									A072201	High Impedance	28/01/2018	28/01/2018
							F24	Insufficient Health Impact Information	A0203	Defective Device	28/01/2018	28/01/2018
									A072201	High Impedance	28/01/2018	28/01/2018
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	28/01/2018	28/01/2018
							F1905	Device Revision or Replacement	A072201	High Impedance	28/01/2018	28/01/2018
									A0203	Defective Device	28/01/2018	28/01/2018
							F24	Insufficient Health Impact Information	A072201	High Impedance	28/01/2018	28/01/2018
									A0203	Defective Device	28/01/2018	28/01/2018
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	28/01/2018	28/01/2018
							F1905	Device Revision or Replacement	A0203	Defective Device	28/01/2018	28/01/2018
									A072201	High Impedance	28/01/2018	28/01/2018
							F24	Insufficient Health Impact Information	A0203	Defective Device	28/01/2018	28/01/2018
									A072201	High Impedance	28/01/2018	28/01/2018
4483	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
									A0705	Battery Problem	13/07/2020	13/07/2020
									A070504	Premature Discharge of Battery	13/07/2020	13/07/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/07/2020	13/07/2020

					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/04/2020	23/04/2020
4486	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		

								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
4487	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
4488	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			

					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4489	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4490	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4491	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2402	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2402	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4498	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2402	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2402	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4499	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
4500	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2986	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4501	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT2986	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/06/2019	
4502	2020	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT1147	Defibrillators and associated devices	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT1150	Defibrillators	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT141	Electrodes/Leads and associated devices	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT145	Cardiovascular devices	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT233	Surgical	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT2406	Implantable	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT2407	Active implantable	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT263	Cardiographs and associated devices	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT2726	Physiological monitoring/measuring devices	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT2727	Active implant devices/ancillaries	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020
							F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT2750	Implantable cardiac electrical stimulators and	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020	04/04/2020

					associated devices	F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT2985	Active	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT3001	Implantable metal	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT3002	Implantable synthetic polymer	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT3006	Implantable inorganic material	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT3007	Implantable ceramic	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT314	Electrically powered	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT321	Long-term surgical invasive	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT449	Generators and associated devices	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT981	Single use	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
					CT983	Surgical invasive	E060110	Ventricular Fibrillation	A070910	Undersensing	04/04/2020
						F02	Death	A070910	Undersensing	04/04/2020	04/04/2020
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	04/04/2020	04/04/2020
4503	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
								A070603	Failure to Charge	23/10/2020	23/10/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020

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						CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
4507	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020	
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	16/04/2020	16/04/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	A070504	Premature Discharge of Battery	16/04/2020	16/04/2020
4508	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem				
								A072201	High Impedance				
						F1905	Device Revision or Replacement	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						F24	Insufficient Health Impact Information	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem				
								A072201	High Impedance				
						F1905	Device Revision or Replacement	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						F24	Insufficient Health Impact Information	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem				
								A072201	High Impedance				
						F1905	Device Revision or Replacement	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						F24	Insufficient Health Impact Information	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem				
								A072201	High Impedance				
						F1905	Device Revision or Replacement	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						F24	Insufficient Health Impact Information	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem				
								A072201	High Impedance				
						F1905	Device Revision or Replacement	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						F24	Insufficient Health Impact Information	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem				
								A072201	High Impedance				
						F1905	Device Revision or Replacement	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						F24	Insufficient Health Impact Information	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem				
								A072201	High Impedance				
						F1905	Device Revision or Replacement	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						F24	Insufficient Health Impact Information	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A0712	Pacing Problem				
								A072201	High Impedance				
						F1905	Device Revision or Replacement	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						F24	Insufficient Health Impact Information	A070909	Oversensing				
								A0712	Pacing Problem				
								A072201	High Impedance				
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT2965	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F24	Insufficient Health Impact Information	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F1905	Device Revision or Replacement	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F24	Insufficient Health Impact Information	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F1905	Device Revision or Replacement	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F24	Insufficient Health Impact Information	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F1905	Device Revision or Replacement	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F24	Insufficient Health Impact Information	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F1905	Device Revision or Replacement	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F24	Insufficient Health Impact Information	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F1905	Device Revision or Replacement	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F24	Insufficient Health Impact Information	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F1905	Device Revision or Replacement	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
							F24	Insufficient Health Impact Information	A070909 A0712 A072201	Oversensing Pacing Problem High Impedance			
4509	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			

					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4513	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4514	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072202	Low Impedance		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
									A072202	Low Impedance		
									A1301	Failure to Read Input Signal		
4515	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
						F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020	
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
									A070504	Premature Discharge of Battery	11/04/2020	11/04/2020

CT2407	Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT3001	Implantable metal	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT3008	Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT314	Electrically powered	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	11/04/2020	11/04/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/04/2020	11/04/2020
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/04/2020	11/04/2020

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CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
CT2966	Implantable cardiac electrical stimulators			A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
CT2985	Active	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
CT3001	Implantable metal			A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
CT3002	Implantable synthetic polymer	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
CT3006	Implantable inorganic material			A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
CT3007	Implantable ceramic	F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
CT314	Electrically powered			A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
CT449	Generators and associated devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
CT981	Single use	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020

							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/06/2020	02/06/2020
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/06/2020	02/06/2020
4517	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT2986	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F19	Surgical Intervention	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F1905	Device Revision or Replacement	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020
							F08	Hospitalization or Prolonged Hospitalization	A0909	Unexpected Therapeutic Results	01/03/2020	01/03/2020

					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT3134	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2019						
					4521	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302						Inappropriate/Inadequate Shock/Stimulation							
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT3134	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					4522	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020
												F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020
												F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020
										CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020
												F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020
		F26	No Health Consequences or Impact	A070504						Premature Discharge of Battery	28/04/2020	28/04/2020					
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	28/04/2020	28/04/2020					
		F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery	28/04/2020	28/04/2020					
		F26	No Health Consequences or Impact	A070504						Premature Discharge of Battery	28/04/2020	28/04/2020					
CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	28/04/2020	28/04/2020					
		F1905	Device Revision or Replacement	A070504						Premature Discharge of Battery	28/04/2020	28/04/2020					
		F26	No Health Consequences or Impact	A070504						Premature Discharge of Battery	28/04/2020	28/04/2020					
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	28/04/2020	28/04/2020					
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/04/2020	28/04/2020										

						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4525	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/04/2020	17/04/2020	

4532	2020	Death	37265	Dual-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT681	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT683	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
							F02	Death	A070910	Underensing	24/03/2020	24/03/2020
									A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
							F02	Death	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	24/03/2020	24/03/2020
									A070910	Underensing	24/03/2020	24/03/2020

								F02	Death	A070909	Oversensing	24/03/2020	24/03/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	24/03/2020	24/03/2020	
									A070909	Oversensing	24/03/2020	24/03/2020	
								F02	Death	A070910	Undersensing	24/03/2020	24/03/2020
									A070909	Oversensing	24/03/2020	24/03/2020	
									A070910	Undersensing	24/03/2020	24/03/2020	
4533	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
4534	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/06/2019		
4535	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
4536	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2020	12/05/2020	

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					CT983	Surgical invasive	F1905 E2403 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A180602 A180602 A180602	Premature End-of-Life Indicator Premature End-of-Life Indicator Premature End-of-Life Indicator	19/04/2020 19/04/2020 19/04/2020	19/04/2020 19/04/2020 19/04/2020					
4538	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT3006	implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	08/01/2020 08/01/2020	08/01/2020 08/01/2020					
					4539	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020
												F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020
										CT1147	Defibrillators and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020
												F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020
										CT1150	Defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020
												F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020
CT141	Electrodes/Leads and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302						Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020					
		F19	Surgical Intervention	A071302						Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020					
CT145	Cardiovascular devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302						Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020					
		F19	Surgical Intervention	A071302						Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020					
CT233	Surgical	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302						Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020					
		F19	Surgical Intervention	A071302						Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020					
CT2406	Implantable	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302						Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020					
		F19	Surgical Intervention	A071302						Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020					
CT2407	Active implantable	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302						Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020					
		F19	Surgical Intervention	A071302						Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020					
CT258	Implantable defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302						Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020					
		F19	Surgical Intervention	A071302						Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020					
CT263	Cardiographs and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302						Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	15/06/2020 15/06/2020	15/06/2020 15/06/2020					
		F19	Surgical Intervention	A071302						Inappropriate/Inadequate Shock/Stimulation	15/06/2020	15/06/2020					

					CT12407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT12727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT12750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT12866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT12985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT13001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT13002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT13006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT13007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4542	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT11147	Defibrillators and associated devices	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT11150	Defibrillators	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT1141	Electrodes/Leads and associated devices	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT1145	Cardiovascular devices	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT1233	Surgical	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT12406	Implantable	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT12407	Active implantable	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT1258	Implantable defibrillators	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT1263	Cardiographs and associated devices	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT12726	Physiological monitoring/measuring devices	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT12727	Active implant devices/ancillaries	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT12866	Implantable cardiac electrical stimulators	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT12985	Active	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT13001	Implantable metal	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT13002	Implantable synthetic polymer	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT13006	Implantable inorganic material	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT13007	Implantable ceramic	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT1314	Electrically powered	E2403 F12 F19	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020 15/05/2020	15/05/2020 15/05/2020 15/05/2020
					CT1321	Long-term surgical invasive	E2403 F12	No Clinical Signs, Symptoms or Conditions Serious Injury/ Illness/ Impairment	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	15/05/2020 15/05/2020	15/05/2020 15/05/2020

								F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
					CT149	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
					CT981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
					CT983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/05/2020	15/05/2020
4543	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT1147	Defibrillators and associated devices		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT1150	Defibrillators		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT1145	Cardiovascular devices		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT1233	Surgical		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT12406	Implantable		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT12407	Active implantable		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT1258	Implantable defibrillators		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT1263	Cardiographs and associated devices		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT12726	Physiological monitoring/measuring devices		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT12727	Active implant devices/ancillaries		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT12750	Implantable cardiac electrical stimulators and associated devices		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT12866	Implantable cardiac electrical stimulators		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT12985	Active		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT13001	Implantable metal		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT13002	Implantable synthetic polymer		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT13006	Implantable inorganic material		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT13007	Implantable ceramic		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
					CT1314	Electrically powered		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		

					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A070909 A071302	Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F1905	Device Revision or Replacement	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F1905	Device Revision or Replacement	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F1905	Device Revision or Replacement	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F1905	Device Revision or Replacement	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
4544	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302 A070909 A071302	Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads end associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F19	Surgical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			

CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		

					CT2750	Implantable cardiac electrical stimulators and associated devices	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2886	Implantable cardiac electrical stimulators	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2985	Active	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT3001	Implantable metal	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT314	Electrically powered	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT981	Single use	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT983	Surgical invasive	F21	Unexpected Deterioration	A071302	Inappropriate/inadequate Shock/Stimulation		
4547	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4548	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4549	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		

					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT259	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
4550	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F14	Prolonged Episode of Care	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F1905	Device Revision or Replacement	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F14	Prolonged Episode of Care	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F1905	Device Revision or Replacement	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F14	Prolonged Episode of Care	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F1905	Device Revision or Replacement	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F14	Prolonged Episode of Care	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F1905	Device Revision or Replacement	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F26	No Health Consequences or Impact	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F14	Prolonged Episode of Care	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					F1905	Device Revision or Replacement	A0712	Pacing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
F26	No Health Consequences or Impact	A0712	Pacing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
F14	Prolonged Episode of Care	A0712	Pacing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
F1905	Device Revision or Replacement	A0712	Pacing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
F14	Prolonged Episode of Care	A0712	Pacing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									

CT258	implantable defibrillators	F1905	Device Revision or Replacement	A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F14	Prolonged Episode of Care	A0712	Pacing Problem		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F14	Prolonged Episode of Care	A0712	Pacing Problem		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2806	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	F14	Prolonged Episode of Care	A0712	Pacing Problem		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	F1905	Device Revision or Replacement	A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F14	Prolonged Episode of Care	A0712	Pacing Problem		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F14	Prolonged Episode of Care	A0712	Pacing Problem		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		

							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F14	Prolonged Episode of Care	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F14	Prolonged Episode of Care	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F14	Prolonged Episode of Care	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F14	Prolonged Episode of Care	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		

				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C1233	Surgical	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C12406	Implantable	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C12407	Active implantable	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C1258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C12727	Active implant devices/ancillaries	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C12866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C12985	Active	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C13001	Implantable metal	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
C13002	Implantable synthetic polymer	E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

							F26	No Health Consequences or Impact	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
4552	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A070909 A0712 A071202 A071302	Oversensing Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E060109	Tachycardia	A070909 A0712 A071202 A071302	Oversensing Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909 A0712 A071202 A071302	Oversensing Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A070909 A0712 A071202 A071302	Oversensing Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E0601	Arrhythmia	A070909 A0712 A071202 A071302	Oversensing Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							E060109	Tachycardia	A070909 A0712 A071202	Oversensing Pacing Problem Inaccurate Synchronization		

CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E0601	Arrhythmia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT145	Cardiovascular devices	E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT233	Surgical	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2406	Implantable	F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		

CT258	Implantable defibrillators	E0601	Arrhythmia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E060109	Tachycardia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E060109	Tachycardia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E060109	Tachycardia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E060109	Tachycardia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E0601	Arrhythmia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E060109	Tachycardia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E0601	Arrhythmia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E060109	Tachycardia	A070909	Oversensing		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		

				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E060109	Tachycardia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2104	Electric Shock	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3006	Implantable inorganic material	E0601	Arrhythmia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E060109	Tachycardia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2104	Electric Shock	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3007	Implantable ceramic	E0601	Arrhythmia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E060109	Tachycardia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2104	Electric Shock	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT314	Electrically powered	E0601	Arrhythmia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E060109	Tachycardia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2104	Electric Shock	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT321	Long-term surgical invasive	E0601	Arrhythmia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E060109	Tachycardia	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2104	Electric Shock	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A0712	Pacing Problem				
				A071202	Inaccurate Synchronization				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT449	Generators and associated devices	E0601	Arrhythmia	A070909	Overensing				
				A0712	Pacing Problem				

					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4555	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A010102	Device Appears to Trigger Rejection	05/06/2019	
4556	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4557	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads end associated devices	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070910	Undersensing		

				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2406	Implantable	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2407	Active implantable	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT258	Implantable defibrillators	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2985	Active	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3001	Implantable metal	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A070910	Undersensing			
				A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			

					CT3006	Implantable inorganic material	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Undersensing		
									A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Undersensing		
									A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Undersensing		
									A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
4558	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020
					CT3001	Implantable metal	F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2020	14/05/2020

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		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT233	Surgical	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2406	Implantable	E060109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT2407	Active implantable	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT258	Implantable defibrillators	E060109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT263	Cardiographs and associated devices	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT2726	Physiological monitoring/measuring devices	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT2985	Active	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT3001	Implantable metal	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT3002	Implantable synthetic polymer	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT3006	Implantable inorganic material	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
CT3007	Implantable ceramic	E060109	Tachycardia	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
		F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		

					CT314	Electrically powered	E060109	Tachycardia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT321	Long-term surgical invasive	E060109	Tachycardia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A071202	Pacing Problem		
									A0712	Inaccurate Synchronization		
					CT449	Generators and associated devices	E060109	Tachycardia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT981	Single use	E060109	Tachycardia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
					CT983	Surgical invasive	E060109	Tachycardia	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
4568	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071202	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
4569	2019	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A24	No Apparent Device Problem	04/06/2019	
4570	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT233	Surgical	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT2406	Implantable	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT2407	Active implantable	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT258	Implantable defibrillators	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT263	Cardiographs and associated devices	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT2726	Physiological monitoring/measuring devices	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT2727	Active implant devices/ancillaries	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT2985	Active	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT3001	Implantable metal	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT3002	Implantable synthetic polymer	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT3006	Implantable inorganic material	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT3007	Implantable ceramic	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT314	Electrically powered	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT321	Long-term surgical invasive	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT449	Generators and associated devices	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT981	Single use	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
					CT983	Surgical invasive	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
4571	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A071202	Inaccurate Synchronization		
4572	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
4573	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT233	Surgical	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT2406	Implantable	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT2985	Active	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0203	Defective Device		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0203	Defective Device		

					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A07054	Defective Device			
					CT981	Single use	F1905	Device Revision or Replacement	A07054	Defective Device			
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A07054	Defective Device			
4574	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
4575	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	28/06/2019		28/06/2019
							F1905	Device Revision or Replacement	A070603	Failure to Charge	28/06/2019		28/06/2019
							F26	No Health Consequences or Impact	A070603	Failure to Charge	28/06/2019		28/06/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	28/06/2019		28/06/2019
							F1905	Device Revision or Replacement	A070603	Failure to Charge	28/06/2019		28/06/2019
							F26	No Health Consequences or Impact	A070603	Failure to Charge	28/06/2019		28/06/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	28/06/2019		28/06/2019
							F1905	Device Revision or Replacement	A070603	Failure to Charge	28/06/2019		28/06/2019
							F26	No Health Consequences or Impact	A070603	Failure to Charge	28/06/2019		28/06/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	28/06/2019		28/06/2019
							F1905	Device Revision or Replacement	A070603	Failure to Charge	28/06/2019		28/06/2019
							F26	No Health Consequences or Impact	A070603	Failure to Charge	28/06/2019		28/06/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	28/06/2019		28/0

					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	28/06/2019	28/06/2019
							F1905	Device Revision or Replacement	A070603	Failure to Charge	28/06/2019	28/06/2019
							F26	No Health Consequences or Impact	A070603	Failure to Charge	28/06/2019	28/06/2019
4576	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2019	
4577	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4578	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/06/2019	
4579	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4580	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4581	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2019	31/12/2019
4582	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4583	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4584	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0512	Unintended Movement	13/08/2019	
4585	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/06/2020	11/06/2020
4586	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/06/2020	11/06/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A27	Appropriate Device Problem Term/Code not Available		

4587	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A27	Appropriate Device Problem Term/Code not Available		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1145	Cardiovascular devices	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1233	Surgical	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12406	Implantable	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12407	Active implantable	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1258	Implantable defibrillators	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12985	Active	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT13001	Implantable metal	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT13002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT13006	Implantable inorganic material	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT13007	Implantable ceramic	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1314	Electrically powered	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1321	Long-term surgical invasive	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1449	Generators and associated devices	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1981	Single use	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1983	Surgical invasive	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
4588	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4589	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4590	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4591	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F14	Prolonged Episode of Care	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F14	Prolonged Episode of Care	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F14	Prolonged Episode of Care	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F14	Prolonged Episode of Care	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F14	Prolonged Episode of Care	A070909	Oversensing		

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					CT321	Long-term surgical invasive	F19	Surgical Intervention	A070909	Oversensing	09/06/2020	09/06/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	09/06/2020	09/06/2020
							F19	Surgical Intervention	A070909	Oversensing	09/06/2020	09/06/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	09/06/2020	09/06/2020
							F19	Surgical Intervention	A070909	Oversensing	09/06/2020	09/06/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	09/06/2020	09/06/2020
							F19	Surgical Intervention	A070909	Oversensing	09/06/2020	09/06/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	09/06/2020	09/06/2020
							F19	Surgical Intervention	A070909	Oversensing	09/06/2020	09/06/2020
4596	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A	Annex A		
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A	Annex A		
					CT1150	Defibrillators	E2401	Insufficient Information	A	Annex A		
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A	Annex A		
					CT145	Cardiovascular devices	E2401	Insufficient Information	A	Annex A		
					CT233	Surgical	E2401	Insufficient Information	A	Annex A		
					CT2406	Implantable	E2401	Insufficient Information	A	Annex A		
					CT2407	Active implantable	E2401	Insufficient Information	A	Annex A		
					CT258	Implantable defibrillators	E2401	Insufficient Information	A	Annex A		
					CT263	Cardiographs and associated devices	E2401	Insufficient Information	A	Annex A		
					CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A	Annex A		
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A	Annex A		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A	Annex A		
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A	Annex A		
					CT2985	Active	E2401	Insufficient Information	A	Annex A		
					CT3001	Implantable metal	E2401	Insufficient Information	A	Annex A		
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A	Annex A		
					CT3006	Implantable inorganic material	E2401	Insufficient Information	A	Annex A		
					CT3007	Implantable ceramic	E2401	Insufficient Information	A	Annex A		
					CT314	Electrically powered	E2401	Insufficient Information	A	Annex A		
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A	Annex A		
					CT449	Generators and associated devices	E2401	Insufficient Information	A	Annex A		
					CT981	Single use	E2401	Insufficient Information	A	Annex A		
					CT983	Surgical invasive	E2401	Insufficient Information	A	Annex A		
4597	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4598	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
					CT1150	Defibrillators	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
					CT145	Cardiovascular devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
							F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021

CT233	Surgical	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT2406	Implantable	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT2407	Active implantable	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT258	Implantable defibrillators	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT263	Cardiographs and associated devices	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT2985	Active	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT3001	Implantable metal	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT3006	Implantable inorganic material	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT3007	Implantable ceramic	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
			F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	2/20/2021
CT314	Electrically powered	E2401	Insufficient Information	A13	Communication or Transmission Problem	2/20/2021	2/20/2021
				A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	2/20/2021	2/20/2021
				A13	Communication or Transmission Problem	2/20/2021	2/20/2021

						F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
				CT321	Long-term surgical invasive	E2401	Insufficient Information	A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						A071201		A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						A071201		A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
						F15	Recognized Device or Procedural Complication	A13	Communication or Transmission Problem	22/02/2021	22/02/2021
				CT449	Generators and associated devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
						A13		A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
						A13		A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
				CT981	Single use	E2401	Insufficient Information	A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						A071201		A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						A13		A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
				CT983	Surgical invasive	E2401	Insufficient Information	A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						A071201		A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
						A13		A13	Communication or Transmission Problem	22/02/2021	22/02/2021
						F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm	22/02/2021	22/02/2021
						A13		A13	Communication or Transmission Problem	22/02/2021	22/02/2021
4599	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
4600	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
					CT1147	Defibrillators and associated devices	F23	Unexpected Medical Intervention	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F23	Unexpected Medical Intervention	A070909	Oversensing		

					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/07/2019	
4607	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

						F15	Recognized Device or Procedural Complication	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F15	Recognized Device or Procedural Complication	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2966	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
4608	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	

					CT2888	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
4009	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/02/2021	03/02/2021
							F26	No Health Consequences or Impact	A070909	Oversensing	03/02/2021	03/02/2021
									A072201	High Impedance	03/02/2021	03/02/2021
4010	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/02/2021	03/02/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4011	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4012	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT2886	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2019	

4613	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2019		
4614	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation				
							F10	Inadequate/Inappropriate Treatment or Diagnostic	A070909	Oversensing			

					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070907	Loss of Threshold		
4618	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4619	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/07/2019	03/07/2019
							F1908	Prolonged Surgery	A070909	Oversensing	03/07/2019	03/07/2019
4620	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
							F12	Serious Injury/Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
							F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
							F12	Serious Injury/Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020

CT1150	Defibrillators	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
CT233	Surgical	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
CT2406	Implantable	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
CT2407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
CT2726	Physiological monitoring/measuring devices	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Overensensing	10/01/2020	10/01/2020

CT2727	Active implant devices/ancillaries	F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
				A070909	Oversensing	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
CT2985	Active	F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
CT3001	Implantable metal	F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
CT3002	Implantable synthetic polymer	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
CT3008	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
CT3007	Implantable ceramic	F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020

						F12	Serious Injury/Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
								A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
					CT321	E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F12	Serious Injury/Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
					CT449	E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F12	Serious Injury/Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
						F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
								A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
					CT981	E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F12	Serious Injury/Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
					CT983	E2104	Electric Shock	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F12	Serious Injury/Illness/ Impairment	A070909	Oversensing	10/01/2020	10/01/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	10/01/2020	10/01/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	10/01/2020	10/01/2020

CT145	Cardiovascular devices	F26	No Health Consequences or Impact	A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical			A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable			A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable			A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators			A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices			A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices			A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries			A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices			A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2966	Implantable cardiac electrical stimulators			A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active			A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal			A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer			A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material			A070909	Oversensing		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic			A070909	Oversensing		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

						F26	No Health Consequences or Impact	A071302 A070909 A071302	Inappropriate/inadequate Shock/Stimulation Oversensing Inappropriate/inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
						F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
						F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
						F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
						F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation	
						F26	No Health Consequences or Impact	A070909 A071302	Oversensing Inappropriate/inadequate Shock/Stimulation		
4623	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping device	E2104	Electric Shock	A0205 A070909 A071302	Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A022301 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F12	Serious Injury/ Illness/ Impairment	A0205 A070909 A071302	Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020
							F19	Surgical Intervention	A022201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F1905	Device Revision or Replacement	A022301 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F12	Serious Injury/ Illness/ Impairment	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F19	Surgical Intervention	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F1905	Device Revision or Replacement	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
					CT1150	Defibrillators	E2104	Electric Shock	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F12	Serious Injury/ Illness/ Impairment	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020
							F19	Surgical Intervention	A072201 A0205 A070909 A071302	High Impedance Packaging Problem Oversensing Inappropriate/inadequate Shock/Stimulation	19/05/2020 19/05/2020 19/05/2020 19/05/2020

				Exposure	A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F12		Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F19		Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F1905		Device Revision or Replacement	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
CT258			Implantable defibrillators	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F12		Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F19		Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F1905		Device Revision or Replacement	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
CT263			Cardiographs and associated devices	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F12		Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F19		Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F1905		Device Revision or Replacement	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
CT2726			Physiological monitoring/measuring devices	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F12		Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F19		Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F1905		Device Revision or Replacement	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
CT2727			Active implant devices/ancillaries	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F12		Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020
					A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
					A072201	High Impedance	19/05/2020	19/05/2020
		F19		Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
					A070909	Oversensing	19/05/2020	19/05/2020

				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
		F1905	Device Revision or Replacement	A072201	High Impedance	19/05/2020	19/05/2020
				A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F12	Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F19	Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F1905	Device Revision or Replacement	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F12	Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F19	Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F1905	Device Revision or Replacement	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
CT2985	Active	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F12	Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F19	Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F1905	Device Revision or Replacement	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
CT3001	Implantable metal	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F12	Serious Injury/ Illness/ Impairment	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F19	Surgical Intervention	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
		F1905	Device Revision or Replacement	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020
				A072201	High Impedance	19/05/2020	19/05/2020
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0205	Packaging Problem	19/05/2020	19/05/2020
				A070909	Oversensing	19/05/2020	19/05/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	19/05/2020	19/05/2020

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					CT2407	Active implantable	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT258	Implantable defibrillators	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT263	Cardiographs and associated devices	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT2726	Physiological monitoring/measuring devices	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT2985	Active	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT3001	Implantable metal	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT3002	Implantable synthetic polymer	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT3006	Implantable inorganic material	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT3007	Implantable ceramic	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT314	Electrically powered	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT321	Long-term surgical invasive	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT449	Generators and associated devices	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT981	Single use	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
					CT983	Surgical invasive	E060109	Tachycardia	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F26	No Health Consequences or Impact	A071202	Inaccurate Synchronization		
4625	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2019	
4626	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/07/2019	
4627	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		

					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
4628	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
							F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator		
4629	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/08/2019	
4630	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	16/02/2021	16/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
							F26	No Health Consequences or Impact	A070909	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
									A071302	Oversensing	16/02/2021	16/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	16/02/2021	16/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
							F26	No Health Consequences or Impact	A070909	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
									A071302	Oversensing	16/02/2021	16/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	16/02/2021	16/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
							F26	No Health Consequences or Impact	A070909	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
									A071302	Oversensing	16/02/2021	16/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	16/02/2021	16/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
							F26	No Health Consequences or Impact	A070909	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
									A071302	Oversensing	16/02/2021	16/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	16/02/2021	16/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
							F26	No Health Consequences or Impact	A070909	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
									A071302	Oversensing	16/02/2021	16/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	16/02/2021	16/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021

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								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
										A070909	Oversensing	16/02/2021	16/02/2021
										A071302	Inappropriate/Inadequate Shock/Stimulation	16/02/2021	16/02/2021
4631	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
							F1903	Device Explanation	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
4632	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A25	No Apparent Adverse Event			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A25	No Apparent Adverse Event			
							F12	Serious Injury/ Illness/ Impairment	A25	No Apparent Adverse Event			
							F14	Prolonged Episode of Care	A25	No Apparent Adverse Event			
4633	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT133	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
4634	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			

					CT263	Cardiographs and associated devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT2726	Physiological monitoring/measuring devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT2727	Active implant devices/ancillaries	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT2866	Implantable cardiac electrical stimulators	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT2985	Active	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT3001	Implantable metal	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT3002	Implantable synthetic polymer	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT3006	Implantable inorganic material	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT3007	Implantable ceramic	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT3134	Electrically powered	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT321	Long-term surgical invasive	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT449	Generators and associated devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT981	Single use	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
					CT983	Surgical invasive	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation Inappropriate/Inadequate Shock/Simulation			
4636	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3134	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
4636	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT1145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			

					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4637	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT1150	Defibrillators	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT233	Surgical	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2406	Implantable	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2407	Active implantable	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2985	Active	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT3001	Implantable metal	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT314	Electrically powered	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905 E2403 F1901	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery		

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[illegible]

							F1905	Device Revision or Replacement	A070602	Delayed Charge Time		
					CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
							E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time		
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
							E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time		
							F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time		
							F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time		
							F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time		
							F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time		
							F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time		
							F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
4643	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/07/2019	
4644	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
4645	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
4646	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		

					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4647	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4648	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070604	Premature Discharge of Battery	26/07/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2019	
4649	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
4650	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070604	Premature Discharge of Battery	08/08/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/08/2019	
4651	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070910	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		

4652	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
						F26	No Health Consequences or Impact	A070910	Undersensing								
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
						F26	No Health Consequences or Impact	A070910	Undersensing								
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
						F26	No Health Consequences or Impact	A070910	Undersensing								
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT233	Surgical	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT2406	Implantable	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT2985	Active	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT981	Single use	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070603	Failure to Charge	30/07/2019						
					4653	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/08/2019	
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/08/2019	
										CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/08/2019	
										CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/08/2019	
										CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/08/2019	
										CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/08/2019	
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery	07/08/2019						
4654	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator						CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
											F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
											F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
										CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
											F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
											F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
											F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
											F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
										CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
											F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
											F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation								
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation								
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation								
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation								
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation								
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation								
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation								
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation								
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation								
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation								
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation								
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation								
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							

4656	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT981	Single use	E2403	No Health Consequences or Impact	A072201	High Impedance							
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					CT983	Surgical invasive	E2403	No Health Consequences or Impact	A072201	High Impedance							
							F26	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
							F26	No Health Consequences or Impact	A072201	High Impedance							
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing							
					4657	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
												F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
												F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
												F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT2966	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
4658	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4659	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4660	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/08/2019	
4661	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		

[illegible]

[illegible]

				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2750	Implantable cardiac electrical stimulators and associated devices	E2336	Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2866	Implantable cardiac electrical stimulators	E2336	Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2985	Active	E2336	Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3001	Implantable metal	E2336	Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3002	Implantable synthetic polymer	E2336	Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3006	Implantable inorganic material	E2336	Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3007	Implantable ceramic	E2336	Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A070909	Overensing			

					CT449	Generators and associated devices	E2336	Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
					CT1981	Single use	E2336	Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
					CT1983	Surgical invasive	E2336	Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
4668	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT3021	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/08/2019	
4669	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							E2006	Erosion	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F19	Surgical Intervention	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F1905	Device Revision or Replacement	A24	No Apparent Device Problem	19/07/2019	19/07/2019
									A24	No Apparent Device Problem	19/07/2019	19/07/2019
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							E2006	Erosion	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F19	Surgical Intervention	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F1905	Device Revision or Replacement	A24	No Apparent Device Problem	19/07/2019	19/07/2019
									A24	No Apparent Device Problem	19/07/2019	19/07/2019
					CT1150	Defibrillators	E1906	Unspecified Infection	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							E2006	Erosion	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F19	Surgical Intervention	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F1905	Device Revision or Replacement	A24	No Apparent Device Problem	19/07/2019	19/07/2019
									A24	No Apparent Device Problem	19/07/2019	19/07/2019
					CT1141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							E2006	Erosion	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F19	Surgical Intervention	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F1905	Device Revision or Replacement	A24	No Apparent Device Problem	19/07/2019	19/07/2019
									A24	No Apparent Device Problem	19/07/2019	19/07/2019
					CT145	Cardiovascular devices	E1906	Unspecified Infection	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							E2006	Erosion	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F19	Surgical Intervention	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F1905	Device Revision or Replacement	A24	No Apparent Device Problem	19/07/2019	19/07/2019
									A24	No Apparent Device Problem	19/07/2019	19/07/2019
					CT233	Surgical	E1906	Unspecified Infection	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							E2006	Erosion	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F19	Surgical Intervention	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F1905	Device Revision or Replacement	A24	No Apparent Device Problem	19/07/2019	19/07/2019
									A24	No Apparent Device Problem	19/07/2019	19/07/2019
					CT2406	Implantable	E1906	Unspecified Infection	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							E2006	Erosion	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F19	Surgical Intervention	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F1905	Device Revision or Replacement	A24	No Apparent Device Problem	19/07/2019	19/07/2019
									A24	No Apparent Device Problem	19/07/2019	19/07/2019
					CT2407	Active implantable	E1906	Unspecified Infection	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							E2006	Erosion	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F19	Surgical Intervention	A24	No Apparent Device Problem	19/07/2019	19/07/2019
							F1905	Device Revision or Replacement	A24	No Apparent Device Problem	19/07/2019	19/07/2019

					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT3301	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT3302	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT3306	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT3307	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT3134	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2008/2019						
					4671	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										F26	No Health Consequences or Impact	A070909	Oversensing				
										CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										F26	No Health Consequences or Impact	A070909	Oversensing				
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										F26	No Health Consequences or Impact	A070909	Oversensing				
										CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										F26	No Health Consequences or Impact	A070909	Oversensing				
										CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										F26	No Health Consequences or Impact	A070909	Oversensing				
										CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										F26	No Health Consequences or Impact	A070909	Oversensing				
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							
F26	No Health Consequences or Impact	A070909	Oversensing														
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							
F26	No Health Consequences or Impact	A070909	Oversensing														
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							
F26	No Health Consequences or Impact	A070909	Oversensing														
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							
F26	No Health Consequences or Impact	A070909	Oversensing														
CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							
F26	No Health Consequences or Impact	A070909	Oversensing														
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							
F26	No Health Consequences or Impact	A070909	Oversensing														
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
F26	No Health Consequences or Impact	A070909	Oversensing														
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
F26	No Health Consequences or Impact	A070909	Oversensing														
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
F26	No Health Consequences or Impact	A070909	Oversensing														
CT3301	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
F26	No Health Consequences or Impact	A070909	Oversensing														
CT3302	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
F26	No Health Consequences or Impact	A070909	Oversensing														
4672	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
					F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation									
CT3301	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation												
F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation														
CT3302	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation												
F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation														

					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
4673	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/09/2020	17/09/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/09/2020	17/09/2020
4674	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	26/09/2019	26/09/2019
4675	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/07/2020	08/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	08/07/2020	08/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2020	08/07/2020
4676	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A071204	No Pacing	09/08/2019	
4677	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
									A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019

CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A0203	Defective Device	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
				A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
		F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
				A090801	Signal Artifact/Noise	29/07/2019	29/07/2019

							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
									A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F08	Hospitalization or Prolonged Hospitalization	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
							F1905	Device Revision or Replacement	A0203	Defective Device	29/07/2019	29/07/2019
									A090801	Signal Artifact/Noise	29/07/2019	29/07/2019
4678	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4679	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/08/2019	
4680	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A0712	Racing Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		

		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
4682	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4683	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/08/2019	

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				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
		E2401	Insufficient Information	A24	No Apparent Device Problem	10/07/2020	10/07/2020
				A1107	Data Problem	10/07/2020	10/07/2020
		F02	Death	A24	No Apparent Device Problem	10/07/2020	10/07/2020
				A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
				A1107	Data Problem	10/07/2020	10/07/2020
CT141	Electrodes/Leads and associated devices	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT145	Cardiovascular devices	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient Information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT1233	Surgical	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient Information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT2406	Implantable	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT12407	Active implantable	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient Information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT1258	Implantable defibrillators	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient Information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT2727	Active implant devices/ancillaries	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT12750	Implantable cardiac electrical stimulators and associated devices	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient Information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT12866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient Information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT2985	Active	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2007	Fail	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		E2401	Insufficient information	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
		F02	Death	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020
CT3001	Implantable metal	E011903	Syncope/Fainting	A1107	Data Problem	10/07/2020	10/07/2020
				A24	No Apparent Device Problem	10/07/2020	10/07/2020

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4691	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2019	
					CT440	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2019	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4692	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4693	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4694	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4696	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT145	Cardiovascular devices			A0705	Battery Problem	13/12/2020	13/12/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT2406	Implantable			A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2020	13/12/2020
				A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2020	13/12/2020
				A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT2407	Active implantable	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT258	Implantable defibrillators			A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2020	13/12/2020
				A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2020	13/12/2020
				A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT263	Cardiographs and associated devices	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT2726	Physiological monitoring/measuring devices			A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2020	13/12/2020
				A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2020	13/12/2020
				A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT2727	Active implant devices/ancillaries	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT2750	Implantable cardiac electrical stimulators and associated devices			A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/12/2020	13/12/2020
				A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/12/2020	13/12/2020
				A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
CT2866	Implantable cardiac electrical stimulators	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020
				A0705	Battery Problem	13/12/2020	13/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2020	13/12/2020

					C1298	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4700	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	C11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					A070504	Premature Discharge of Battery	09/07/2020	09/07/2020				
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					C11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					C1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					C1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					C1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					C12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					C12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
					A071102	Failure to Interrogate	09/07/2020	09/07/2020				
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020		
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
				A071102	Failure to Interrogate	09/07/2020	09/07/2020					
				A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
				A071102	Failure to Interrogate	09/07/2020	09/07/2020					
				A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
				A071102	Failure to Interrogate	09/07/2020	09/07/2020					
				A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
				A071102	Failure to Interrogate	09/07/2020	09/07/2020					
				A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
				A071102	Failure to Interrogate	09/07/2020	09/07/2020					
				A070504	Premature Discharge of Battery	09/07/2020	09/07/2020					
F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020							
A071102	Failure to Interrogate	09/07/2020	09/07/2020									

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					CT149	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	09/07/2020	09/07/2020
									A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
							F1901	Additional Surgery	A071102	Failure to Interrogate	09/07/2020	09/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/07/2020	09/07/2020
									A071102	Failure to Interrogate	09/07/2020	09/07/2020
4701	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	01/08/2019	01/08/2019		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	01/08/2019	01/08/2019		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	01/08/2019	01/08/2019		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	01/08/2019	01/08/2019		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	01/08/2019	01/08/2019		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	01/08/2019	01/08/2019		
4706	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery											
F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery											
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery									
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery									
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery									
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery									
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery									
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery									
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery									
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
4707	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity				
							CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity		

					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070902	Increased Sensitivity			
4708	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070910	Undersensing			

					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
									A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
47/09	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/08/2019	
47/10	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographic and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

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					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																							
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																							
							F26	No Health Consequences or Impact	A070909	Oversensing																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																							
							CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					
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						CT983	Surgical invasive		E2104	Electric Shock	A070909	Oversensing																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					
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					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A	Annex A		
4717	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/07/2020	15/07/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	15/07/2020	15/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/07/2020	15/07/2020
4718	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							A1601	Device Alarm System	A070504	Premature Discharge of Battery		

					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A1601	Device Alarm System			
									A070504	Premature Discharge of Battery			
									A1601	Device Alarm System			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A1601	Device Alarm System			
									A070504	Premature Discharge of Battery			
									A1601	Device Alarm System			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A1601	Device Alarm System			
									A070504	Premature Discharge of Battery			
									A1601	Device Alarm System			
4719	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			

						F1905	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
					C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/07/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/07/2020	03/07/2020

4726	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2886	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2886	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4727	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A2304	Off-Label Use		
									A070909	Oversensing		

		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A2304	Off-Label Use		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A090801	Signal Artifact/Noise		

							F26	No Health Consequences or Impact	A2304 A070909 A090801 A2304	Off-Label Use Oversensing Signal Artifact/Noise Off-Label Use		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A2304	Oversensing Signal Artifact/Noise Off-Label Use		
							F26	No Health Consequences or Impact	A070909 A090801 A2304	Oversensing Signal Artifact/Noise Off-Label Use		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A2304	Oversensing Signal Artifact/Noise Off-Label Use		
							F26	No Health Consequences or Impact	A070909 A090801 A2304	Oversensing Signal Artifact/Noise Off-Label Use		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A2304	Oversensing Signal Artifact/Noise Off-Label Use		
							F26	No Health Consequences or Impact	A070909 A090801 A2304	Oversensing Signal Artifact/Noise Off-Label Use		
4728	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT1147	Defibrillators and associated devices	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT1150	Defibrillators	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT141	Electrodes/Leads and associated devices	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT145	Cardiovascular devices	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT233	Surgical	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT2406	Implantable	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT2407	Active implantable	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT258	Implantable defibrillators	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT263	Cardiographs and associated devices	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT2726	Physiological monitoring/measuring devices	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT2727	Active implant devices/ancillaries	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT2866	Implantable cardiac electrical stimulators	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT2965	Active	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT3001	Implantable metal	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT3002	Implantable synthetic polymer	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT3006	Implantable inorganic material	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT3007	Implantable ceramic	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT314	Electrically powered	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT321	Long-term surgical invasive	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT449	Generators and associated devices	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT981	Single use	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
					CT983	Surgical invasive	E0503	Embolism/Embolus	A24	No Apparent Device Problem		
4729	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT1147	Defibrillators and associated devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT1150	Defibrillators	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT141	Electrodes/Leads and associated devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT145	Cardiovascular devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT233	Surgical	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT2406	Implantable	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT2407	Active implantable	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT258	Implantable defibrillators	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT263	Cardiographs and associated devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT2726	Physiological monitoring/measuring devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT2727	Active implant devices/ancillaries	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020 25/08/2020	25/08/2020 25/08/2020 25/08/2020
					CT2866	Implantable cardiac electrical stimulators	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	25/08/2020 25/08/2020	25/08/2020 25/08/2020

						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020	25/08/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT3007	implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/08/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/08/2020
4730	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3001	implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	
4731	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	

					CT449	Generators and associated devices	F1905 E2403 F1901 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	19/07/2020 19/07/2020 19/07/2020 19/07/2020	19/07/2020 19/07/2020 19/07/2020 19/07/2020
					CT981	Single use	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	19/07/2020 19/07/2020 19/07/2020	19/07/2020 19/07/2020 19/07/2020
					CT983	Surgical invasive	E2403 F1901 F1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	19/07/2020 19/07/2020 19/07/2020	19/07/2020 19/07/2020 19/07/2020
4733	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F10 F26	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
4734	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A071102 A070504 A071102	Premature Discharge of Battery Failure to Interrogate Premature Discharge of Battery Failure to Interrogate	21/07/2020 21/07/2020 21/07/2020 21/07/2020	21/07/2020 21/07/2020 21/07/2020 21/07/2020
4735	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT1147	Defibrillators and associated devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT1150	Defibrillators	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT141	Electrodes/Leads and associated devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT145	Cardiovascular devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT233	Surgical	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT2406	Implantable	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT2407	Active implantable	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT258	Implantable defibrillators	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT263	Cardiographs and associated devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		
					CT2727	Active implant devices/ancillaries	E2104 E2403 F26	Electric Shock No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4736	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation	21/01/2020	21/01/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	21/01/2020	21/01/2020

					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4740	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4741	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4742	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	07/07/2020	07/07/2020
							F14	Prolonged Episode of Care	A0712	Pacing Problem	07/07/2020	07/07/2020
							F1905	Device Revision or Replacement	A0712	Pacing Problem	07/07/2020	07/07/2020
							F1908	Prolonged Surgery	A0712	Pacing Problem	07/07/2020	07/07/2020
									A070909	Oversensing	07/07/2020	07/07/2020
									A0712	Pacing Problem	07/07/2020	07/07/2020
									A070909	Oversensing	07/07/2020	07/07/2020
									A0712	Pacing Problem	07/07/2020	07/07/2020
4743	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060109	Tachycardia	A070909	Oversensing		
					CT1150	Defibrillators	E060109	Tachycardia	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A070909	Oversensing		
					CT145	Cardiovascular devices	E060109	Tachycardia	A070909	Oversensing		
					CT233	Surgical	E060109	Tachycardia	A070909	Oversensing		
					CT2406	Implantable	E060109	Tachycardia	A070909	Oversensing		
					CT2407	Active implantable	E060109	Tachycardia	A070909	Oversensing		
					CT258	Implantable defibrillators	E060109	Tachycardia	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A070909	Oversensing		
					CT2985	Active	E060109	Tachycardia	A070909	Oversensing		
					CT3001	Implantable metal	E060109	Tachycardia	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E060109	Tachycardia	A070909	Oversensing		
					CT3006	Implantable inorganic material	E060109	Tachycardia	A070909	Oversensing		
					CT3007	Implantable ceramic	E060109	Tachycardia	A070909	Oversensing		
					CT314	Electrically powered	E060109	Tachycardia	A070909	Oversensing		
					CT321	Long-term surgical invasive	E060109	Tachycardia	A070909	Oversensing		
					CT449	Generators and associated devices	E060109	Tachycardia	A070909	Oversensing		
					CT981	Single use	E060109	Tachycardia	A070909	Oversensing		
					CT983	Surgical invasive	E060109	Tachycardia	A070909	Oversensing		
4744	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographic and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4745	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4746	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	09/09/2019	
4747	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4748	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
4749	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A070101	Failure to Capture		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					F26	No Health Consequences or Impact	A070909	Oversensing									
					4750	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E011903	Syncope/Fainting	A0712	Pacing Problem		
														A071202	Inaccurate Synchronization		
														A071302	Inappropriate/Inadequate Shock/Stimulation		
A0909	Unexpected Therapeutic Results																
E060109	Tachycardia	A0712	Pacing Problem														
		A071202	Inaccurate Synchronization														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A0909	Unexpected Therapeutic Results														
E2104	Electric Shock	A0712	Pacing Problem														
		A071202	Inaccurate Synchronization														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A0909	Unexpected Therapeutic Results														
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem														
		A071202	Inaccurate Synchronization														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A0909	Unexpected Therapeutic Results														
F14	Prolonged Episode of Care	A0712	Pacing Problem														
		A071202	Inaccurate Synchronization														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A0909	Unexpected Therapeutic Results														
F23	Unexpected Medical Intervention	A0712	Pacing Problem														
		A071202	Inaccurate Synchronization														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A0909	Unexpected Therapeutic Results														
CT1150	Defibrillators	E011903	Syncope/Fainting	A0712						Pacing Problem							
				A071202						Inaccurate Synchronization							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A0909						Unexpected Therapeutic Results							
		E060109	Tachycardia	A0712						Pacing Problem							
				A071202						Inaccurate Synchronization							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A0909						Unexpected Therapeutic Results							
		E2104	Electric Shock	A0712						Pacing Problem							
				A071202						Inaccurate Synchronization							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A0909						Unexpected Therapeutic Results							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712						Pacing Problem							
				A071202						Inaccurate Synchronization							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A0909						Unexpected Therapeutic Results							
		F14	Prolonged Episode of Care	A0712						Pacing Problem							
				A071202						Inaccurate Synchronization							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A0909						Unexpected Therapeutic Results							
		F23	Unexpected Medical Intervention	A0712						Pacing Problem							
A071202	Inaccurate Synchronization																
A071302	Inappropriate/Inadequate Shock/Stimulation																
A0909	Unexpected Therapeutic Results																
CT141	Electrodes/Leads and associated devices	E011903	Syncope/Fainting	A0712						Pacing Problem							
				A071202						Inaccurate Synchronization							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A0909						Unexpected Therapeutic Results							
		E060109	Tachycardia	A0712						Pacing Problem							
				A071202						Inaccurate Synchronization							
				A071302	Inappropriate/Inadequate Shock/Stimulation												
				A0909	Unexpected Therapeutic Results												
		E2104	Electric Shock	A0712	Pacing Problem												
				A071202	Inaccurate Synchronization												
				A071302	Inappropriate/Inadequate Shock/Stimulation												
				A0909	Unexpected Therapeutic Results												

CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		A0909	Unexpected Therapeutic Results				
		F14	Prolonged Episode of Care	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
	A0909			Unexpected Therapeutic Results			
	E011903	Syncope/Fainting	A0712	Pacing Problem			
			A071202	Inaccurate Synchronization			
			A071302	Inappropriate/Inadequate Shock/Stimulation			
			A0909	Unexpected Therapeutic Results			
		E060109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
A0909				Unexpected Therapeutic Results			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				
	F14	Prolonged Episode of Care	A0712	Pacing Problem			
			A071202	Inaccurate Synchronization			
			A071302	Inappropriate/Inadequate Shock/Stimulation			
			A0909	Unexpected Therapeutic Results			
	F23	Unexpected Medical Intervention	A0712	Pacing Problem			
			A071202	Inaccurate Synchronization			
			A071302	Inappropriate/Inadequate Shock/Stimulation			
			A0909	Unexpected Therapeutic Results			

CT1233	Surgical	E011903	Syncope/Fainting	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E060109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
			A071202	Inaccurate Synchronization			
			A071302	Inappropriate/Inadequate Shock/Stimulation			
			A0909	Unexpected Therapeutic Results			
		F14	Prolonged Episode of Care	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		

CT2406	Implantable	E011903	Syncope/Fainting	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E060109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
			A071202	Inaccurate Synchronization			
			A071302	Inappropriate/Inadequate Shock/Stimulation			
			A0909	Unexpected Therapeutic Results			
		F14	Prolonged Episode of Care	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		

CT2407	Active implantable	E011903	Syncope/Fainting	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		

CT2866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				
		E080109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
A071202	Inaccurate Synchronization						
A071302	Inappropriate/Inadequate Shock/Stimulation						
A0909	Unexpected Therapeutic Results						
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				
F14	Prolonged Episode of Care	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				
F23	Unexpected Medical Intervention	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				

CT2985	Active	E011903	Syncope/Fainting	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E080109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				
F14	Prolonged Episode of Care	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				
F23	Unexpected Medical Intervention	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				

CT3001	Implantable metal	E011903	Syncope/Fainting	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E080109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				
F14	Prolonged Episode of Care	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				
F23	Unexpected Medical Intervention	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				

CT3002	Implantable synthetic polymer	E011903	Syncope/Fainting	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E080109	Tachycardia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem				
		A071202	Inaccurate Synchronization				
		A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0909	Unexpected Therapeutic Results				

					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
			F14	Prolonged Episode of Care	A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
			F23	Unexpected Medical Intervention	A0909	Unexpected Therapeutic Results		
					A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
CT3006	Implantable inorganic material	E011903	Syncope/Fainting		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		E060109	Tachycardia		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F14	Prolonged Episode of Care		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
CT3007	Implantable ceramic	E011903	Syncope/Fainting		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		E060109	Tachycardia		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F14	Prolonged Episode of Care		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
CT314	Electrically powered	E011903	Syncope/Fainting		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		E060109	Tachycardia		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F14	Prolonged Episode of Care		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
CT321	Long-term surgical invasive	E011903	Syncope/Fainting		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A0909	Unexpected Therapeutic Results		
		E060109	Tachycardia		A0712	Pacing Problem		
					A071202	Inaccurate Synchronization		
					A071302	Inappropriate/Inadequate Shock/Stimulation		

			E2104	Electric Shock	A0909 A0712 A071202 A071302 A0909	Unexpected Therapeutic Results Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F14	Prolonged Episode of Care		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
	CT449	Generators and associated devices	E011903	Syncopal/Fainting	A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		E060109	Tachycardia		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		E2104	Electric Shock		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F14	Prolonged Episode of Care		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
	CT981	Single use	E011903	Syncopal/Fainting	A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		E060109	Tachycardia		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		E2104	Electric Shock		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F14	Prolonged Episode of Care		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
	CT983	Surgical invasive	E011903	Syncopal/Fainting	A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		E060109	Tachycardia		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		E2104	Electric Shock		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F14	Prolonged Episode of Care		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		
		F23	Unexpected Medical Intervention		A0712 A071202 A071302 A0909	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Unexpected Therapeutic Results		

4753	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F26 E2403 F14 F26	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Prolonged Episode of Care No Health Consequences or Impact	A070909 A071208 A071208 A071208	Oversensing Pacing Intermittently Pacing Intermittently Pacing Intermittently		
4754	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F26 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT1150	Defibrillators	F26 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT141	Electrodes/Leads and associated devices	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT145	Cardiovascular devices	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT233	Surgical	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT2406	Implantable	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT2407	Active implantable	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT258	Implantable defibrillators	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT2727	Active implant devices/ancillaries	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT2985	Active	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT3001	Implantable metal	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT3002	Implantable synthetic polymer	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT3006	Implantable inorganic material	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT3007	Implantable ceramic	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT314	Electrically powered	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT321	Long-term surgical invasive	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT449	Generators and associated devices	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT981	Single use	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
					CT983	Surgical invasive	F15 E2403	No Clinical Signs, Symptoms or Conditions Recognized Device or Procedural Complication	A0712 A0712	Pacing Problem Pacing Problem		
4755	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT1147	Defibrillators and associated devices	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT1150	Defibrillators	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT141	Electrodes/Leads and associated devices	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT145	Cardiovascular devices	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT233	Surgical	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT2406	Implantable	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT2407	Active implantable	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT258	Implantable defibrillators	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT263	Cardiographs and associated devices	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT2726	Physiological monitoring/measuring devices	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT2727	Active implant devices/ancillaries	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT2985	Active	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT3001	Implantable metal	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT3002	Implantable synthetic polymer	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT3006	Implantable inorganic material	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT3007	Implantable ceramic	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT314	Electrically powered	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT321	Long-term surgical invasive	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		
					CT449	Generators and associated devices	F2303 E2403	Medication Required No Clinical Signs, Symptoms or Conditions	A0712 A0712	Pacing Problem Pacing Problem		

					CT981	Single use	E2303	Medication Required	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT983	Surgical invasive	E2303	Medication Required	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							E2303	Medication Required	A0712	Pacing Problem		
4756	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4757	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020

							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/08/2020	05/08/2020
4758	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
4759	2019	Death	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT1150	Defibrillators			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT141	Electrodes/Leads and associated devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT145	Cardiovascular devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT233	Surgical			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT2406	Implantable			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT2407	Active implantable			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT258	Implantable defibrillators			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT2727	Active implant devices/ancillaries			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT2750	Implantable cardiac electrical stimulators and associated devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT2866	Implantable cardiac electrical stimulators			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT2985	Active			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT3001	Implantable metal			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT3002	Implantable synthetic polymer			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT3006	Implantable inorganic material			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT3007	Implantable ceramic			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT314	Electrically powered			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT321	Long-term surgical invasive			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT449	Generators and associated devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT981	Single use			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
					CT983	Surgical invasive			A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2019	06/09/2019
4760	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
						F26	No Health Consequences or Impact		A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
						F26	No Health Consequences or Impact		A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
						F26	No Health Consequences or Impact		A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
						F26	No Health Consequences or Impact		A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020

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							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event	23/07/2020	23/07/2020
									A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
							F26	No Health Consequences or Impact	A070910	Undersensing	23/07/2020	23/07/2020
									A072202	Low Impedance	23/07/2020	23/07/2020
									A25	No Apparent Adverse Event	23/07/2020	23/07/2020
4761	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2965	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4762	2020	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A0709	Device Sensing Problem	01/07/2020	01/07/2020
							F02	Death	A0709	Device Sensing Problem	01/07/2020	01/07/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/07/2020	01/07/2020
4763	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4764	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT1449	Generators and associated devices	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
					C1981	Single use	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A26	Insufficient Device Problem Information		
4766	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4767	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1276	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4768	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/07/2020	28/07/2020

					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2019	
4777	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4778	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4779	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		

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4788	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Premature Discharge of Battery	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020		
							A071302	Inappropriate/Inadequate Shock/Stimulation	07/10/2020	07/10/2020		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F24	Insufficient Health Impact Information	A072201	High Impedance							
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
		F24	Insufficient Health Impact Information	A072201	High Impedance							
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
		F24	Insufficient Health Impact Information	A072201	High Impedance							
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
		F24	Insufficient Health Impact Information	A072201	High Impedance							
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
		F24	Insufficient Health Impact Information	A072201	High Impedance							
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							

						CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/12/2020	19/12/2020
						E2403	No Clinical Signs, Symptoms or Conditions	F1905	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/12/2020	
						F1905	Device Revision or Replacement	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/12/2020	
4793	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT1146	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT2727	Active implant devices/incinerates	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/09/2019		
4794	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/incinerates	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
4795	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1146	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/incinerates	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			

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								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1901	Additional Surgery	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1901	Additional Surgery	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1901	Additional Surgery	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1901	Additional Surgery	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
4798	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E060110	Ventricular Fibrillation	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							F26	No Health Consequences or Impact	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
					CT1147	Defibrillators and associated devices	E060109	Tachycardia	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E060110	Ventricular Fibrillation	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							F26	No Health Consequences or Impact	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
					CT1150	Defibrillators	E060109	Tachycardia	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E060110	Ventricular Fibrillation	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							F26	No Health Consequences or Impact	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E060110	Ventricular Fibrillation	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							F26	No Health Consequences or Impact	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
					CT145	Cardiovascular devices	E060109	Tachycardia	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E060110	Ventricular Fibrillation	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							F26	No Health Consequences or Impact	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
					CT233	Surgical	E060109	Tachycardia	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E060110	Ventricular Fibrillation	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation		17/02/2021	17/02/2021
							F26	No Health Consequences or Impact	A0712	Pacing Problem		17/02/2021	17/02/2021
									A071202	Inaccurate Synchronization		17/02/2021	17/02/2021

[illegible]

[illegible]

						F26	No Health Consequences or Impact	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
					CT449	Generators and associated devices	E060109	Tachycardia	A0712	Pacing Problem	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						E060110	Ventricular Fibrillation	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						F26	No Health Consequences or Impact	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
					CT981	Single use	E060109	Tachycardia	A0712	Pacing Problem	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						E060110	Ventricular Fibrillation	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						F26	No Health Consequences or Impact	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
					CT983	Surgical invasive	E060109	Tachycardia	A0712	Pacing Problem	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						E060110	Ventricular Fibrillation	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						F26	No Health Consequences or Impact	A0712	Pacing Problem	17/02/2021	17/02/2021
								A071202	Inaccurate Synchronization	17/02/2021	17/02/2021
								A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
4799	2019	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A071102	Failure to Interrogate	26/09/2019
4800	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	

4801	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/09/2019						
4802	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
					4803	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
												F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
												F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
										CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT1150	Defibrillators	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT145	Cardiovascular devices	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT233	Surgical	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT2406	Implantable	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT2407	Active implantable	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT258	Implantable defibrillators	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT2985	Active	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT3001	Implantable metal	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
		F1905	Device Revision or Replacement	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302						Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020					

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
						CT3006	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
						CT3007	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
						CT314	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
						CT321	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
						CT449	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
						CT981	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
						CT983	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/08/2020	21/08/2020
4804	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F14	Prolonged Episode of Care		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F23	Unexpected Medical Intervention		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						CT1147	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F14	Prolonged Episode of Care		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F23	Unexpected Medical Intervention		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						CT1150	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F14	Prolonged Episode of Care		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F23	Unexpected Medical Intervention		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						CT141	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		
						F14	Prolonged Episode of Care		A070909	Oversensing		
									A0712	Pacing Problem		
									A071209	Extracardiac Stimulation		
									A072201	High Impedance		

CT145	Cardiovascular devices	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT233	Surgical	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT2406	Implantable	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT2407	Active implantable	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT258	Implantable defibrillators	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT263	Cardiographs and associated devices	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		

				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT2726	Physiological monitoring/measuring devices	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT2727	Active implant devices/ancillaries	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT2750	Implantable cardiac electrical stimulators and associated devices	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT2866	Implantable cardiac electrical stimulators	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
CT2985	Active	E0138	Undesired Nerve Stimulation	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F14	Prolonged Episode of Care	A070909	Oversensing		
				A0712	Pacing Problem		
				A071209	Extracardiac Stimulation		
				A072201	High Impedance		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A0712	Pacing Problem		

CT3001	Implantable metal	E0138	Undesired Nerve Stimulation	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT3002	Implantable synthetic polymer	E0138	Undesired Nerve Stimulation	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT3006	Implantable inorganic material	E0138	Undesired Nerve Stimulation	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT3007	Implantable ceramic	E0138	Undesired Nerve Stimulation	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT314	Electrically powered	E0138	Undesired Nerve Stimulation	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F14	Prolonged Episode of Care	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT321	Long-term surgical invasive	E0138	Undesired Nerve Stimulation	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071209	Extracardiac Stimulation		
				A072201	High Impedance		
				A070909	Oversensing		

						F14	Prolonged Episode of Care	A072201 A070909 A0712 A071209 A072201	High Impedance Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F23	Unexpected Medical Intervention	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
				CT449	Generators and associated devices	E0138	Undesired Nerve Stimulation	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F08	Hospitalization or Prolonged Hospitalization	A072201 A070909 A0712 A071209 A072201	High Impedance Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F14	Prolonged Episode of Care	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F23	Unexpected Medical Intervention	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
				CT981	Single use	E0138	Undesired Nerve Stimulation	A072201 A070909 A0712 A071209 A072201	High Impedance Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F08	Hospitalization or Prolonged Hospitalization	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F14	Prolonged Episode of Care	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F23	Unexpected Medical Intervention	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
				CT983	Surgical invasive	E0138	Undesired Nerve Stimulation	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F08	Hospitalization or Prolonged Hospitalization	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F14	Prolonged Episode of Care	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
						F23	Unexpected Medical Intervention	A070909 A0712 A071209 A072201	Oversensing Pacing Problem Extracardiac Stimulation High Impedance			
4805	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070102 A072201	Failure to Capture High Capture Threshold High Impedance		
						F15	Recognized Device or Procedural Complication	A070101 A070102 A072201	Failure to Capture High Capture Threshold High Impedance			
4806	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery		
					CT1150	Defibrillators	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT233	Surgical	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2406	Implantable	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2407	Active implantable	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery		

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						F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/08/2020	14/08/2020
4809	2020	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/08/2020	14/08/2020
						E2401	Insufficient Information	A0709	Device Sensing Problem		
						F02	Death	A0709	Device Sensing Problem		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
4810	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	F1905	Device Revision or Replacement	A010402	Migration		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
4811	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT141	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT145	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
								A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT233	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
								A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT2406	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					F19	Surgical Intervention	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
4812	2019		All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
4813	2019		All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4814	2019		All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4815	2020		All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A0712	Pacing Problem		

						F26	No Health Consequences or Impact	A070910	Undersensing			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
4816	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

4817	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A05	Mechanical Problem	01/07/2019	
4818	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4819	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		

					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
4820	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT141	Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2019	
4821	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/08/2020	13/08/2020
							F1905	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/08/2020	13/08/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/08/2020	13/08/2020
4822	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT233	Surgical	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT2406	Implantable	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT2985	Active	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT981	Single use	F1905	Device Revision or Replacement	A160105	False Alarm		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A160105	False Alarm		
4823	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT081	Single use	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT193	Surgical invasive	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
4824	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A0712	Pacing Problem			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A0712	Pacing Problem			
					CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A0712	Pacing Problem			
					CT233	Surgical	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A0712	Pacing Problem			
					CT2406	Implantable	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A0712	Pacing Problem			
					CT2407	Active implantable	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A0712	Pacing Problem			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A0712	Pacing Problem			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A0712	Pacing Problem			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			

					CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3001	implantable metal	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3002	implantable synthetic polymer	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT314	Electrically powered	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT981	Single use	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
4826	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
4827	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A090801	Signal Artifact/Noise		
					CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
4828	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture			
									A070909	Oversensing			
							F15	Recognized Device or Procedural Complication	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			
									A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture			
									A070909	Oversensing			
							F15	Recognized Device or Procedural Complication	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture			
									A070909	Oversensing			
							F15	Recognized Device or Procedural Complication	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			
									A1301	Failure to Read Input Signal			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture			
									A070909	Oversensing			
							F15	Recognized Device or Procedural Complication	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			
									A1301	Failure to Read Input Signal			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture			
									A070909	Oversensing			
							F15	Recognized Device or Procedural Complication	A1301	Failure to Read Input Signal			
									A070101	Failure to Capture			
									A070909	Oversensing			

CT2406	Implantable	F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
		E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F15	Recognized Device or Procedural Complication	A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
		F26	No Health Consequences or Impact	A070101	Failure to Capture				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
				A070101	Failure to Capture				
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
				A1301	Failure to Read Input Signal				
				A070909	Oversensing				
				A1301	Failure to Read Input Signal				
		F15	Recognized Device or Procedural Complication	A070101	Failure to Capture				

									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact		A070101	Failure to Capture		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
4829	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		

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								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic		E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered		E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive		E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices		E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use		E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive		E2117	Twiddlers Syndrome	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
4830	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT2726	Physiological monitoring/measuring devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020
					CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/04/2020	30/04/2020

					CT983	Surgical invasive	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator		
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator		
4832	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator		
4833	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		</

									A071302	Inappropriate/inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
						F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
								A0712	Pacing Problem			
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/inadequate Shock/Stimulation			
								A0712	Pacing Problem			
						F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation			
								A0712	Pacing Problem			
								A071302	Inappropriate/inadequate Shock/Stimulation			
4834	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	30/09/2019	
4835	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
4836	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4637	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/09/2020	24/09/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	24/09/2020	24/09/2

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						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/09/2020	17/09/2020
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/09/2020	17/09/2020
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/09/2020	17/09/2020
4841	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
4842	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		

						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/08/2020	09/08/2016
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/08/2020	09/08/2016
						CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/08/2020	09/08/2016
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/08/2020	09/08/2016
						CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/08/2020	09/08/2016
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/08/2020	09/08/2016
4845	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/09/2020	10/09/2020	
4846	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1901	Additional Surgery	A070504	Premature Discharge of Battery	10/09/2020	10/09/2020	
4847	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
4848	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021	
						CT1150	Defibrillators	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT233	Surgical	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT2407	Active implantable	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT258	Implantable defibrillators	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT2727	Active implant devices/ancillaries	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT2866	Implantable cardiac electrical stimulators	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT3001	Implantable metal	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT3006	Implantable inorganic material	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT321	Long-term surgical invasive	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT981	Single use	F1901	Additional Surgery	A070603	Failure to Charge	08/01/2021	08/01/2021
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	08/01/2021	08/01/2021
4849	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT581	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4050	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A	Annex A		
4051	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT233	Surgical	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT2985	Active	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT581	Single use	F1905	Device Revision or Replacement	A070909	Oversensing		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070909	Oversensing		
4052	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT1147	Defibrillators and associated devices	F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/09/2020	11/09/2020
4853	2020	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT145	Cardiovascular devices	E2104	Electric Shock	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT233	Surgical	E2104	Electric Shock	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2406	Implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2407	Active implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			

CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		E2104	Electric Shock	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		E2104	Electric Shock	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT3001	Implantable metal	E2104	Electric Shock	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		E2104	Electric Shock	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			
		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A1301	Failure to Read Input Signal			

					CT314	Electrically powered	E2104	Electric Shock	A1301 A0709 A071302 A1301	Failure to Read Input Signal Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT449	Generators and associated devices	E2104	Electric Shock	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT981	Single use	E2104	Electric Shock	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT983	Surgical invasive	E2104	Electric Shock	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A0709 A071302 A1301	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
4854	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4855	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070908	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4856	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
									A0508	Noise, Audible	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
									A0508	Noise, Audible	19/11/2020	19/11/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
									A0508	Noise, Audible	19/11/2020	19/11/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
									A0508	Noise, Audible	19/11/2020	19/11/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
									A0508	Noise, Audible	19/11/2020	19/11/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
									A0508	Noise, Audible	19/11/2020	19/11/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
									A0508	Noise, Audible	19/11/2020	19/11/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020
									A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
							F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
									A0508	Noise, Audible	19/11/2020	19/11/2020
F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/11/2020			19/11/2020					
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/11/2020	19/11/2020					
				A070504	Premature Discharge of Battery	19/11/2020	19/11/2020					
		F19	Surgical Intervention	A0508	Noise, Audible	19/11/2020	19/11/2020					
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020					
				A0508	Noise, Audible	19/11/2020	19/11/2020					

								F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/11/2020	19/11/2020
					C1981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery	19/11/2020 19/11/2020	19/11/2020 19/11/2020
								F19	Surgical Intervention	A0508 A070504	Noise, Audible Premature Discharge of Battery	19/11/2020 19/11/2020	19/11/2020 19/11/2020
					C1983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504	Noise, Audible Premature Discharge of Battery	19/11/2020 19/11/2020	19/11/2020 19/11/2020
								F19	Surgical Intervention	A0508 A070504	Noise, Audible Premature Discharge of Battery	19/11/2020 19/11/2020	19/11/2020 19/11/2020
4857	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	C1258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070101 A072201	Failure to Capture High Impedance	19/11/2020 19/11/2020	19/11/2020 19/11/2020
								F24	Insufficient Health Impact Information	A070101 A072201	Failure to Capture High Impedance		
4858	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	C1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1150	Defibrillators		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C12406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C12407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C12727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C12750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C12866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C12985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C13001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C13002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C13006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C13007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
					C1983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2022	20/06/2022
4859	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	C1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
								F24	Insufficient Health Impact Information	A070909 A0712	Oversensing Pacing Problem		
					C1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
								F24	Insufficient Health Impact Information	A070909 A0712	Oversensing Pacing Problem		
					C1141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem		
								F24	Insufficient Health Impact Information	A070909	Oversensing		

					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A070909	Oversensing		
									A0712	Pacing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A070909	Oversensing		
4860	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
							E0602	Cardiac Arrest	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F12	Serious Injury/Illness/Impairment	A071202	Inaccurate Synchronization		
					CT1150	Defibrillators	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
							E0602	Cardiac Arrest	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F12	Serious Injury/Illness/Impairment	A071202	Inaccurate Synchronization		
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
							E0602	Cardiac Arrest	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F12	Serious Injury/Illness/Impairment	A071202	Inaccurate Synchronization		
					CT145	Cardiovascular devices	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
							E0602	Cardiac Arrest	A071202	Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
							F12	Serious Injury/Illness/Impairment	A071202	Inaccurate Synchronization		

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					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2020	01/09/2020
4865	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2019	
4866	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT2407	Active implantable	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
4867	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/10/2019	
4868	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060110 E2403 F12	Ventricular Fibrillation No Clinical Signs, Symptoms or Conditions Serious Injury/Illness/ Impairment	A071202 A071202 A071202	Inaccurate Synchronization Inaccurate Synchronization Inaccurate Synchronization	01/10/2019	

4669	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
4670	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4871	2019	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F21	Unexpected Deterioration	A0712	Pacing Problem		
4872	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem	21/10/2019	
4873	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2020	31/03/2020

						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
							F26	No Health Consequences or Impact	A072201	High Impedance	
4876	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021</

							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
					CT449	Generators and associated devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
					CT981	Single use	F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
4877	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
4878	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4879	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
4890	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Health Consequences or Impact	A070909	Oversensing		
							F26	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Health Consequences or Impact	A070909	Oversensing		
							F26	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT081	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT193	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4081	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		

4882	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F28	No Health Consequences or Impact	A070909	Oversensing		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
4883	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4884	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT11147	Defibrillators and associated devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT11150	Defibrillators	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1145	Cardiovascular devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1233	Surgical	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12406	Implantable	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12407	Active implantable	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1258	Implantable defibrillators	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1263	Cardiographs and associated devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12726	Physiological monitoring/measuring devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12727	Active implant devices/ancillaries	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12866	Implantable cardiac electrical stimulators	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12985	Active	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT13001	Implantable metal	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT13002	Implantable synthetic polymer	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT13006	Implantable inorganic material	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT13007	Implantable ceramic	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1314	Electrically powered	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1321	Long-term surgical invasive	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1449	Generators and associated devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1981	Single use	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4885	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4886	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	Premature Discharge of Battery	16/09/2020	16/09/2020
							PT301	Additional Surgery	A070504	Premature Discharge of Battery	16/09/2020	16/09/2020
4887	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT3006	Implantable inorganic material	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT3007	Implantable ceramic	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT314	Electrically powered	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT321	Long-term surgical invasive	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT449	Generators and associated devices	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT981	Single use	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT983	Surgical invasive	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
4888	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F26 F1905	No Health Consequences or Impact Device Revision or Replacement	A070909 A070504	Oversensing Premature Discharge of Battery		
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
4889	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4890	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT1150	Defibrillators	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT145	Cardiovascular devices	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT233	Surgical	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT2406	Implantable	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT2407	Active implantable	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT258	Implantable defibrillators	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT2985	Active	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT3001	Implantable metal	F05	Delay to Treatment/ Therapy	A070909	Oversensing		

					CT3002	Implantable synthetic polymer	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT3006	Implantable inorganic material	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT3007	Implantable ceramic	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT314	Electrically powered	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT321	Long-term surgical invasive	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT449	Generators and associated devices	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT981	Single use	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
					CT983	Surgical invasive	F05	Delay to Treatment/ Therapy	A070909	Oversensing		
4891	2020	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

4895	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4896	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation							
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation								
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation								
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation								
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation								
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation								
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation								
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation								
4897	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery								
					4898	2020	Death	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071102	Failure to Interrogate	09/09/2020	09/09/2020	
												E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	09/09/2020	09/09/2020	
														A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020	
												F02	Death	A071102	Failure to Interrogate	09/09/2020	09/09/2020	
														A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020	
										CT1150	Defibrillators	E0601	Arrhythmia	A071102	Failure to Interrogate	09/09/2020	09/09/2020	
												E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	09/09/2020	09/09/2020	
														A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020	
												F02	Death	A071102	Failure to Interrogate	09/09/2020	09/09/2020	
														A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020	
										CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071102	Failure to Interrogate	09/09/2020	09/09/2020	
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
		E2403	No Clinical Signs, Symptoms or Conditions	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
		F02	Death	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
CT145	Cardiovascular devices	E0601	Arrhythmia	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
		E2403	No Clinical Signs, Symptoms or Conditions	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
		F02	Death	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
CT233	Surgical	E0601	Arrhythmia	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
		E2403	No Clinical Signs, Symptoms or Conditions	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
		F02	Death	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
CT2406	Implantable	E0601	Arrhythmia	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
		E2403	No Clinical Signs, Symptoms or Conditions	A071102						Failure to Interrogate	09/09/2020	09/09/2020						
				A160503						Inappropriate or Unexpected Reset	09/09/2020	09/09/2020						
		F02	Death	A071102	Failure to Interrogate	09/09/2020	09/09/2020											
				A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020											
CT2407	Active implantable	E0601	Arrhythmia	A071102	Failure to Interrogate	09/09/2020	09/09/2020											
				A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020											
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	09/09/2020	09/09/2020											
				A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020											
		F02	Death	A071102	Failure to Interrogate	09/09/2020	09/09/2020											
				A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020											
CT258	Implantable defibrillators	E0601	Arrhythmia	A071102	Failure to Interrogate	09/09/2020	09/09/2020											
				A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020											
		E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	09/09/2020	09/09/2020											
				A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020											
		F02	Death	A071102	Failure to Interrogate	09/09/2020	09/09/2020											
				A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020											
		CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A071102	Failure to Interrogate	09/09/2020	09/09/2020									
						A160503	Inappropriate or Unexpected Reset	09/09/2020	09/09/2020									

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4907	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
4908	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	02/10/2020	02/10/2020							
4909	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
							CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing
					CT145	Cardiovascular devices					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing
							CT233	Surgical			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing
									CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing
					CT2407	Active implantable					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing

					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4910	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/10/2019	
4911	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4912	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT2406	Implantable	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3134	Electrically powered	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4013	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/10/2020	13/10/2020

					CT314	Electrically powered	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/10/2020 13/10/2020 13/10/2020	13/10/2020 13/10/2020 13/10/2020
					CT321	Long-term surgical invasive	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/10/2020 13/10/2020 13/10/2020	13/10/2020 13/10/2020 13/10/2020
					CT449	Generators and associated devices	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/10/2020 13/10/2020 13/10/2020	13/10/2020 13/10/2020 13/10/2020
					CT981	Single use	E2403 F19 F1905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/10/2020 13/10/2020 13/10/2020	13/10/2020 13/10/2020 13/10/2020
					CT983	Surgical invasive	F1905 E2403 F19	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	13/10/2020 13/10/2020 13/10/2020	13/10/2020 13/10/2020 13/10/2020
4914	2020	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	F1905 E2104 E2403 F08	Device Revision or Replacement Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A070504 A071302 A071302 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	13/10/2020 	13/10/2020
					CT1147	Defibrillators and associated devices	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT1150	Defibrillators	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT141	Electrodes/Leads and associated devices	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT145	Cardiovascular devices	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT233	Surgical	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT2406	Implantable	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT2407	Active implantable	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT258	Implantable defibrillators	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT263	Cardiographs and associated devices	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT2726	Physiological monitoring/measuring devices	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT2727	Active implant devices/incinerates	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT2866	Implantable cardiac electrical stimulators	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT2985	Active	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT3001	Implantable metal	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT3002	Implantable synthetic polymer	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT3006	Implantable inorganic material	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT3007	Implantable ceramic	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT314	Electrically powered	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT321	Long-term surgical invasive	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT449	Generators and associated devices	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT981	Single use	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
					CT983	Surgical invasive	E2104 E2403 F08	Electric Shock No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation	 	
4915	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		

					CT1150	Defibrillators	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1145	Cardiovascular devices	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1233	Surgical	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT2406	Implantable	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1258	Implantable defibrillators	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT12727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT12750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT12866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT12985	Active	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT13001	Implantable metal	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT13002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT13006	Implantable inorganic material	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT13007	Implantable ceramic	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1314	Electrically powered	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1321	Long-term surgical invasive	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT4449	Generators and associated devices	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1981	Single use	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1983	Surgical invasive	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
4016	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT4449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4017	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
4018	2020	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070810	Undersensing	25/09/2020	25/09/2020
							F02	Death	A071301	Failure to Deliver Shock/Stimulation	25/09/2020	25/09/2020
									A070910	Undersensing	25/09/2020	25/09/2020
									A071301	Failure to Deliver Shock/Stimulation	25/09/2020	25/09/2020
4019	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/09/2020	30/09/2020

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				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
CT258	Implantable defibrillators	E2104	Electric Shock	A090801	Signal Artifact/Noise				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
CT263	Cardiographs and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A090801	Signal Artifact/Noise				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A090801	Signal Artifact/Noise				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A090801	Signal Artifact/Noise				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
CT2985	Active	E2104	Electric Shock	A090801	Signal Artifact/Noise				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				
				A090801	Signal Artifact/Noise				
		F15	Recognized Device or Procedural Complication	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A072201	High Impedance				

CT3001	Implantable metal	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F15	Recognized Device or Procedural Complication	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F15	Recognized Device or Procedural Complication	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT3006	Implantable inorganic material	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F15	Recognized Device or Procedural Complication	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT3007	Implantable ceramic	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F15	Recognized Device or Procedural Complication	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT314	Electrically powered	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F15	Recognized Device or Procedural Complication	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT321	Long-term surgical invasive	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F15	Recognized Device or Procedural Complication	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT449	Generators and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
		F15	Recognized Device or Procedural Complication	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		
CT981	Single use	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A072201	High Impedance		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise			
							F15	Recognized Device or Procedural Complication	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise			
				CT983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise				
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise				
						F15	Recognized Device or Procedural Complication	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise				
4625	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT1150	Defibrillators	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT141	Electrodes/Leads and associated devices	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT145	Cardiovascular devices	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT233	Surgical	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT2406	Implantable	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT2407	Active implantable	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT258	Implantable defibrillators	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT2727	Active implant devices/ancillaries	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT2866	Implantable cardiac electrical stimulators	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT2985	Active	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT3001	Implantable metal	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT3002	Implantable synthetic polymer	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT3006	Implantable inorganic material	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT3007	Implantable ceramic	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT314	Electrically powered	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT321	Long-term surgical invasive	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT449	Generators and associated devices	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT981	Single use	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
					CT983	Surgical invasive	F21	Unexpected Deterioration	A24	No Apparent Device Problem			
4626	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
4627	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing			
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing			
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing			
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing			
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing			
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing			
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			

						CT2727	Active implant devices/ancillaries	F10	Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
4028	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem		9/7/1/2019	
4029	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4030	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		13/11/2019	13/11/2019
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/11/2019	13/11/2019
4031	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT1150	Defibrillators	F26	No Health Consequences or Impact	A070909	Oversensing		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

						CT233	Surgical	F26	No Health Consequences or Impact	A070909	Oversensing		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						CT2406	Implantable	F26	No Health Consequences or Impact	A070909	Oversensing		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT2896	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3008	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
4932	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
4933	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021	
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
						CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/01/2021	06/01/2021

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CT141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT145	Cardiovascular devices	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT233	Surgical	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT2406	Implantable	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT2407	Active implantable	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT2985	Active	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT3001	Implantable metal	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT314	Electrically powered	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
CT449	Generators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
		E060102	Atrial Fibrillation	A072201	High Impedance		
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT981	Single use	E060102	Atrial Fibrillation	A072201	High Impedance			
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT983	Surgical invasive	E060102	Atrial Fibrillation	A072201	High Impedance			
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
4936	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060102	Atrial Fibrillation	A0712	Pacing Problem				
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								E2104	Electric Shock	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F26	No Health Consequences or Impact	A0909	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
						CT1150	Defibrillators	E060102	Atrial Fibrillation	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								E2104	Electric Shock	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F26	No Health Consequences or Impact	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
						CT1141	Electrodes/Leads and associated devices	E060102	Atrial Fibrillation	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								E2104	Electric Shock	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F26	No Health Consequences or Impact	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
						CT1145	Cardiovascular devices	E060102	Atrial Fibrillation	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								E2104	Electric Shock	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F26	No Health Consequences or Impact	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
						CT1233	Surgical	E060102	Atrial Fibrillation	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								E2104	Electric Shock	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F26	No Health Consequences or Impact	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
						CT2406	Implantable	E060102	Atrial Fibrillation	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								E2104	Electric Shock	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								F26	No Health Consequences or Impact	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
						CT2407	Active implantable	E060102	Atrial Fibrillation	A0712	Pacing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A0909	Unexpected Therapeutic Results				
								E2104	Electric Shock	A0712	Pacing Problem			

				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
CT258	Implantable defibrillators	E060102	Atrial Fibrillation	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
CT2727	Active implant devices/ancillaries	E060102	Atrial Fibrillation	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060102	Atrial Fibrillation	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
CT2866	Implantable cardiac electrical stimulators	E060102	Atrial Fibrillation	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
CT2985	Active	E060102	Atrial Fibrillation	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
CT3001	Implantable metal	E060102	Atrial Fibrillation	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
CT3002	Implantable synthetic polymer	E060102	Atrial Fibrillation	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0909	Unexpected Therapeutic Results		

					CT141 Electrodes/Leads and associated devices E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT145 Cardiovascular devices E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT233 Surgical E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT2406 Implantable E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT2407 Active implantable E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT258 Implantable defibrillators E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT2727 Active implant devices/ancillaries E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT2750 Implantable cardiac electrical stimulators and associated devices E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT2866 Implantable cardiac electrical stimulators E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT2985 Active E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT3001 Implantable metal E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT3002 Implantable synthetic polymer E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT3006 Implantable inorganic material E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT3007 Implantable ceramic E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT314 Electrically powered E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT321 Long-term surgical invasive E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT440 Generators and associated devices E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT981 Single use E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					CT983 Surgical invasive E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
4940	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147 Defibrillators and associated devices E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT1150 Defibrillators E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT141 Electrodes/Leads and associated devices E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT145 Cardiovascular devices E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT233 Surgical E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT2406 Implantable E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT2407 Active implantable E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT258 Implantable defibrillators E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT2727 Active implant devices/ancillaries E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT2750 Implantable cardiac electrical stimulators and associated devices E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT2866 Implantable cardiac electrical stimulators E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT2985 Active E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT3001 Implantable metal E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT3002 Implantable synthetic polymer E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT3006 Implantable inorganic material E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT3007 Implantable ceramic E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT314 Electrically powered E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT321 Long-term surgical invasive E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
					CT983 Surgical invasive E2403 No Clinical Signs, Symptoms or Conditions A071302 Inappropriate/Inadequate Shock/Stimulation		
4941	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258 Implantable defibrillators E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing		
					F26 No Health Consequences or Impact A070909 Oversensing		
					A0712 Pacing Problem A090801 Signal Artifact/Noise		
					A0712 Pacing Problem A090801 Signal Artifact/Noise		
4942	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010 Cardiovascular physiology analysis/mapping devices E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT1147 Defibrillators and associated devices E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT1150 Defibrillators E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT141 Electrodes/Leads and associated devices E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT145 Cardiovascular devices E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT233 Surgical E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT2406 Implantable E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT2407 Active implantable E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT258 Implantable defibrillators E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT263 Cardiographs and associated devices E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT2726 Physiological monitoring/measuring devices E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT2727 Active implant devices/ancillaries E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT2750 Implantable cardiac electrical stimulators and associated devices E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT2866 Implantable cardiac electrical stimulators E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT2985 Active E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT3001 Implantable metal E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT3002 Implantable synthetic polymer E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT3006 Implantable inorganic material E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT3007 Implantable ceramic E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT314 Electrically powered E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		
					F26 No Health Consequences or Impact A072201 High Impedance		
					CT321 Long-term surgical invasive E2403 No Clinical Signs, Symptoms or Conditions A072201 High Impedance		

					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
4043	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2019	
4044	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A110206	Application Program Version or Upgrade Problem		
4045	2019	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/11/2019	
4046	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2019	
4047	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2019	
4048	2019	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4949	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
4950	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
4951	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A071302 A090801	Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A090801	Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise		
							F15	Recognized Device or Procedural Complication	A071302 A090801	Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise		
4952	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

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					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
4058	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A0712	Pacing Problem		
4059	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/10/2020	06/10/2020
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	06/10/2020	06/10/2020

					CT2726	Physiological monitoring/measuring devices	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT2727	Active implant devices/ancillaries	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT2866	Implantable cardiac electrical stimulators	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT2985	Active	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT3001	Implantable metal	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT3002	Implantable synthetic polymer	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT3006	Implantable inorganic material	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT3007	Implantable ceramic	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT1314	Electrically powered	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT1321	Long-term surgical invasive	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT1449	Generators and associated devices	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT981	Single use	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
					CT983	Surgical invasive	F1901 E2403 F10	Additional Surgery No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 06/10/2020 06/10/2020	06/10/2020 06/10/2020 06/10/2020
4060	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1901 E2403 F1905	Additional Surgery No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	06/10/2020 07/10/2020 07/10/2020	06/10/2020 07/10/2020 07/10/2020
					CT1147	Defibrillators and associated devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT1150	Defibrillators	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT1141	Electrodes/Leads and associated devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT1145	Cardiovascular devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT1233	Surgical	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT2406	Implantable	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT2407	Active implantable	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT1258	Implantable defibrillators	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT263	Cardiographs and associated devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT2726	Physiological monitoring/measuring devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT2727	Active implant devices/ancillaries	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT2866	Implantable cardiac electrical stimulators	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT2985	Active	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT3001	Implantable metal	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT3002	Implantable synthetic polymer	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020
					CT3006	Implantable inorganic material	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	07/10/2020 07/10/2020	07/10/2020 07/10/2020

					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
					CT081	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
					CT193	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2020	07/10/2020
4061	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT2727	Active implant devices/anncillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
									A0909	Unexpected Therapeutic Results		

					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0909	Unexpected Therapeutic Results		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F24	Insufficient Health Impact Information	A0909	Unexpected Therapeutic Results		
4962	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/09/2020	23/09/2020
							F14	Prolonged Episode of Care	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/09/2020	23/09/2020
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/09/2020	23/09/2020
							F1908	Prolonged Surgery	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/09/2020	23/09/2020
4963	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/10/2020	23/10/2020
4964	2020	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070910	Undersensing	16/10/2020	16/10/2020
									A070912	Incorrect Interpretation of Signal	16/10/2020	16/10/2020
							F02	Death	A071301	Failure to Deliver Shock/Stimulation	16/10/2020	16/10/2020
									A070910	Undersensing	16/10/2020	16/10/2020
									A070912	Incorrect Interpretation of Signal	16/10/2020	16/10/2020
									A071301	Failure to Deliver Shock/Stimulation	16/10/2020	16/10/2020
4965	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/06/2020	10/06/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/06/2020	10/06/2020
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	10/06/2020	10/06/2020
4966	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

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[illegible]

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
4969	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A0712	Pacing Problem		
4970	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery		
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery		
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery		
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery		
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery		
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery			
						F15	Recognized Device or Procedural Complication	A070504	Premature Discharge of Battery			
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
4971	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	25/09/2020	25/09/2020
									A072201	High Impedance	25/09/2020	25/09/2020
						F19	Surgical Intervention	A04	Material Integrity Problem	25/09/2020	25/09/2020	
									A072201	High Impedance	25/09/2020	25/09/2020
						F1905	Device Revision or Replacement	A04	Material Integrity Problem	25/09/2020	25/09/2020	
									A072201	High Impedance	25/09/2020	25/09/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	25/09/2020	25/09/2020
									A072201	High Impedance	25/09/2020	25/09/2020
						F19	Surgical Intervention	A04	Material Integrity Problem	25/09/2020	25/09/2020	
									A072201	High Impedance	25/09/2020	25/09/2020
						F1905	Device Revision or Replacement	A04	Material Integrity Problem	25/09/2020	25/09/2020	
									A072201	High Impedance	25/09/2020	25/09/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	25/09/2020	25/09/2020
									A072201	High Impedance	25/09/2020	25/09/2020

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					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
4976	2020	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal	04/11/2020	04/11/2020
									A071301	Failure to Deliver Shock/Stimulation	04/11/2020	04/11/2020
									A25	No Apparent Adverse Event	04/11/2020	04/11/2020
						F21	Unexpected Deterioration	A070912	Incorrect Interpretation of Signal	04/11/2020	04/11/2020	
									A071301	Failure to Deliver Shock/Stimulation	04/11/2020	04/11/2020
									A25	No Apparent Adverse Event	04/11/2020	04/11/2020
						F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal	04/11/2020	04/11/2020	
									A071301	Failure to Deliver Shock/Stimulation	04/11/2020	04/11/2020
									A25	No Apparent Adverse Event	04/11/2020	04/11/2020
4977	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A150206	Difficult to Insert		
							F26	No Health Consequences or Impact	A150206	Difficult to Insert		
4978	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020

4079	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020		
									F1901	Additional Surgery	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/11/2020	09/11/2020
					CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									F24	Insufficient Health Impact Information	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									F24	Insufficient Health Impact Information	A070909	Oversensing		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									F24	Insufficient Health Impact Information	A070909	Oversensing		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									F24	Insufficient Health Impact Information	A070909	Oversensing		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing				
											A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
4980	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	14/10/2020	14/10/2020

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						F1905	Device Revision or Replacement	A070909	Overensing	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070909	Overensing	25/06/2021	25/06/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	25/06/2021	25/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070909	Overensing	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	25/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070909	Overensing	25/06/2021	25/06/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	25/06/2021	25/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070909	Overensing	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	25/06/2021	25/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070909	Overensing	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
						F1905	Device Revision or Replacement	A070909	Overensing	25/06/2021	25/06/2021
4984	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator	
						E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator		
4985	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
						F26	No Health Consequences or Impact	A070909	Overensing		
4986	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020
F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020							
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020							
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020					
F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020							
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/11/2020	12/11/2020							
4967	2020	All other reportable incidents	37265		CT1147	Defibrillators and associated devices	E060102	Atrial Fibrillation	A0712	Pacing Problem		
					E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem				
					F26	No Health Consequences or Impact	A0712	Pacing Problem				
					CT1150	Defibrillators	E060102	Atrial Fibrillation	A0712	Pacing Problem		
					E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem				
					F26	No Health Consequences or Impact	A0712	Pacing Problem				
					CT1141	Electrodes/Leads and associated devices	E060102	Atrial Fibrillation	A0712	Pacing Problem		
					E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem				
					F26	No Health Consequences or Impact	A0712	Pacing Problem				
					CT1145	Cardiovascular devices	E060102	Atrial Fibrillation	A0712	Pacing Problem		
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT233	Surgical	E060102	Atrial Fibrillation	A0712	Pacing Problem							
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT2406	Implantable	E060102	Atrial Fibrillation	A0712	Pacing Problem							
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT2407	Active implantable	E060102	Atrial Fibrillation	A0712	Pacing Problem							
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT258	Implantable defibrillators	E060102	Atrial Fibrillation	A0712	Pacing Problem							
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT2727	Active implant devices/ancillaries	E060102	Atrial Fibrillation	A0712	Pacing Problem							
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT2750	Implantable cardiac electrical stimulators and associated devices	E060102	Atrial Fibrillation	A0712	Pacing Problem							
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT2866	Implantable cardiac electrical stimulators	E060102	Atrial Fibrillation	A0712	Pacing Problem							
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT2985	Active	E060102	Atrial Fibrillation	A0712	Pacing Problem							
E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
F26	No Health Consequences or Impact	A0712	Pacing Problem									
CT3001	Implantable metal	E060102	Atrial Fibrillation	A0712	Pacing Problem							

						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
						F26	No Health Consequences or Impact	A0909	Unexpected Therapeutic Results		
								A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
					CT3002	implantable synthetic polymer	E060102	Atrial Fibrillation	A0712	Pacing Problem	
								A0909	Unexpected Therapeutic Results		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
						F26	No Health Consequences or Impact	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
					CT3006	Implantable inorganic material	E060102	Atrial Fibrillation	A0712	Pacing Problem	
								A0909	Unexpected Therapeutic Results		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
						F26	No Health Consequences or Impact	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
					CT3007	implantable ceramic	E060102	Atrial Fibrillation	A0712	Pacing Problem	
								A0909	Unexpected Therapeutic Results		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
						F26	No Health Consequences or Impact	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
					CT314	Electrically powered	E060102	Atrial Fibrillation	A0712	Pacing Problem	
								A0909	Unexpected Therapeutic Results		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
						F26	No Health Consequences or Impact	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
					CT321	Long-term surgical invasive	E060102	Atrial Fibrillation	A0712	Pacing Problem	
								A0909	Unexpected Therapeutic Results		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
						F26	No Health Consequences or Impact	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
					CT449	Generators and associated devices	E060102	Atrial Fibrillation	A0712	Pacing Problem	
								A0909	Unexpected Therapeutic Results		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
						F26	No Health Consequences or Impact	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
					CT981	Single use	E060102	Atrial Fibrillation	A0712	Pacing Problem	
								A0909	Unexpected Therapeutic Results		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
						F26	No Health Consequences or Impact	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
					CT983	Surgical invasive	E060102	Atrial Fibrillation	A0712	Pacing Problem	
								A0909	Unexpected Therapeutic Results		
						E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
						F26	No Health Consequences or Impact	A0712	Pacing Problem		
								A0909	Unexpected Therapeutic Results		
4988	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2886	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	

					F26	No Health Consequences or Impact	A072201	High Impedance		
					E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance		
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
					F26	No Health Consequences or Impact	A072201	High Impedance		
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
					F26	No Health Consequences or Impact	A072201	High Impedance		
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
					F26	No Health Consequences or Impact	A072201	High Impedance		
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
					F26	No Health Consequences or Impact	A072201	High Impedance		
4989	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	C11010	Cardiovascular physiology analysis/mapping device	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery 15/12/2020 15/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge

								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/11/2020	27/11/2020	
4994	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
4995	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
									A072201	High Impedance			
									A12	Connection Problem			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A072201	High Impedance			
									A12	Connection Problem			
4996	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm			
					CT1150	Defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm			
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm			

[illegible]

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CT1150	Defibrillators	F1905	Device Revision or Replacement	A0508	Noise, Audible	01/12/2020	01/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
CT1141	Electrodes/Leads and associated devices	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
CT1145	Cardiovascular devices			A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
CT2406	Implantable			A0508	Noise, Audible	01/12/2020	01/12/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
CT258	Implantable defibrillators			A0508	Noise, Audible	01/12/2020	01/12/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
CT2750	Implantable cardiac electrical stimulators and associated devices			A0508	Noise, Audible	01/12/2020	01/12/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
CT2985	Active			A0508	Noise, Audible	01/12/2020	01/12/2020
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020
				A0508	Noise, Audible	01/12/2020	01/12/2020
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2020	01/12/2020

					CT3001	Implantable metal	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104 F10 F26	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure No Health Consequences or Impact	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
5010	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact Device Revision or Replacement	A13 A13 A070504	Communication or Transmission Problem Communication or Transmission Problem Premature Discharge of Battery		
5011	2020	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT1147	Defibrillators and associated devices	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT1150	Defibrillators	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT141	Electrodes/Leads and associated devices	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT145	Cardiovascular devices	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT233	Surgical	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT2406	Implantable	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT2407	Active implantable	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT258	Implantable defibrillators	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT263	Cardiographs and associated devices	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT2726	Physiological monitoring/measuring devices	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT2727	Active implant devices/ancillaries	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT2866	Implantable cardiac electrical stimulators	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT2985	Active	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT3001	Implantable metal	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT3002	Implantable synthetic polymer	E2403 F19 F905	No Clinical Signs, Symptoms or Conditions Surgical Intervention Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020
					CT3006	Implantable inorganic material	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	03/11/2020	03/11/2020

						CT3007	Implantable ceramic	F1905 Device Revision or Replacement A070504 Premature Discharge of Battery E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery F19 Surgical Intervention A070504 Premature Discharge of Battery F1905 Device Revision or Replacement A070504 Premature Discharge of Battery	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020
						CT314	Electrically powered	E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery F19 Surgical Intervention A070504 Premature Discharge of Battery F1905 Device Revision or Replacement A070504 Premature Discharge of Battery	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020
						CT321	Long-term surgical invasive	E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery F19 Surgical Intervention A070504 Premature Discharge of Battery F1905 Device Revision or Replacement A070504 Premature Discharge of Battery	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020
						CT449	Generators and associated devices	E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery F19 Surgical Intervention A070504 Premature Discharge of Battery F1905 Device Revision or Replacement A070504 Premature Discharge of Battery	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020
						CT981	Single use	F1905 Device Revision or Replacement A070504 Premature Discharge of Battery E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery F19 Surgical Intervention A070504 Premature Discharge of Battery F1905 Device Revision or Replacement A070504 Premature Discharge of Battery	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020
						CT983	Surgical invasive	E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery F19 Surgical Intervention A070504 Premature Discharge of Battery F1905 Device Revision or Replacement A070504 Premature Discharge of Battery	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020	03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020 03/11/2020
5012	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT1147	Defibrillators and associated devices	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT1150	Defibrillators	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT141	Electrodes/Leads and associated devices	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT145	Cardiovascular devices	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT233	Surgical	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT2406	Implantable	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT2407	Active implantable	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT258	Implantable defibrillators	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT263	Cardiographs and associated devices	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT2726	Physiological monitoring/measuring devices	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT2727	Active implant devices/ancillaries	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT2985	Active	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT3001	Implantable metal	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT3002	Implantable synthetic polymer	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance F26 No Health Consequences or Impact A070909 Oversensing A072201 High Impedance			
					CT3006	Implantable inorganic material	E2403 No Clinical Signs, Symptoms or Conditions A070909 Oversensing A072201 High Impedance			

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					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
5017	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT1150	Defibrillators	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT145	Cardiovascular devices	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT233	Surgical	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2406	Implantable	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2407	Active implantable	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2886	Implantable cardiac electrical stimulators	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2985	Active	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT3001	Implantable metal	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT3007	Implantable ceramic	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT314	Electrically powered	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT449	Generators and associated devices	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT981	Single use	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT983	Surgical invasive	E060103	Atrial Flutter	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
5018	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2020	26/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2020	26/11/2020

					CT983	Surgical invasive	E2403 F27	Problem Identified During Non-Clinical Procedure No Clinical Signs, Symptoms or Conditions Problem Identified During Non-Clinical Procedure	A0908 A0909 A0908	Incorrect, Inadequate or Improper Result or Readings Incorrect, Inadequate or Improper Result or Readings Incorrect, Inadequate or Improper Result or Readings	10/11/2020 10/11/2020 10/11/2020	10/11/2020 10/11/2020 10/11/2020
5021	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT1147	Defibrillators and associated devices	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT1150	Defibrillators	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT141	Electrodes/Leads and associated devices	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT145	Cardiovascular devices	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT1233	Surgical	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT12406	Implantable	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT12407	Active implantable	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT1258	Implantable defibrillators	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT1263	Cardiographs and associated devices	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT12726	Physiological monitoring/measuring devices	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT12727	Active implant devices/ancillaries	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT12866	Implantable cardiac electrical stimulators	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT12985	Active	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT3001	Implantable metal	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT3002	Implantable synthetic polymer	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT3006	Implantable inorganic material	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT3007	Implantable ceramic	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT314	Electrically powered	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT321	Long-term surgical invasive	E2403 F19	No Clinical Signs, Symptoms or Conditions Surgical Intervention	A0705 A070504	Battery Problem Premature Discharge of Battery	22/12/2020 22/12/2020	22/12/2020 22/12/2020
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/12/2020	22/12/2020

							F19	Surgical Intervention	A0705	Battery Problem	22/12/2020	22/12/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/12/2020	22/12/2020
							F19	Surgical Intervention	A0705	Battery Problem	22/12/2020	22/12/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	22/12/2020	22/12/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/12/2020	22/12/2020
							F19	Surgical Intervention	A0705	Battery Problem	22/12/2020	22/12/2020
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	22/12/2020	22/12/2020
5022	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2020	26/11/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2020	26/11/2020
5023	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5024	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT314	Electrically powered	E0801 F02	Arrhythmia Death	A0908 A0908	Incorrect, Inadequate or Improper Result or Readings Incorrect, Inadequate or Improper Result or Readings	29/11/2020 29/11/2020	29/11/2020 29/11/2020
					CT321	Long-term surgical invasive	E0601 F02	Arrhythmia Death	A0908 A0908	Incorrect, Inadequate or Improper Result or Readings Incorrect, Inadequate or Improper Result or Readings	29/11/2020 29/11/2020	29/11/2020 29/11/2020
					CT449	Generators and associated devices	E0801 F02	Arrhythmia Death	A0908 A0908	Incorrect, Inadequate or Improper Result or Readings Incorrect, Inadequate or Improper Result or Readings	29/11/2020 29/11/2020	29/11/2020 29/11/2020
					CT981	Single use	E0601 F02	Arrhythmia Death	A0908 A0908	Incorrect, Inadequate or Improper Result or Readings Incorrect, Inadequate or Improper Result or Readings	29/11/2020 29/11/2020	29/11/2020 29/11/2020
					CT983	Surgical invasive	E0601 F02	Arrhythmia Death	A0908 A0908	Incorrect, Inadequate or Improper Result or Readings Incorrect, Inadequate or Improper Result or Readings	29/11/2020 29/11/2020	29/11/2020 29/11/2020
5027	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1233	Surgical	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A070909 A071302 A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104 F08 F10 F15	Electric Shock Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure Recognized Device or Procedural Complication	A071302 A070909 A071302 A070909 A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing		

CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries			A070909	Oversensing		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators			A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal			A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3002	Implantable synthetic polymer	F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material			A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered			A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT321	Long-term surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT1449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
5028	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12868	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5029	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

[illegible]

[illegible]

		F24	Insufficient Health Impact Information	A0712	Pacing Problem		
CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	F24	Insufficient Health Impact Information	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT263	Cardiographs and associated devices	F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT2727	Active implant devices/ancillaries	F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT2866	Implantable cardiac electrical stimulators	F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2885	Active	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT3001	Implantable metal	F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT3006	Implantable inorganic material	F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT314	Electrically powered	F24	Insufficient Health Impact Information	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F24	Insufficient Health Impact Information	A0712	Pacing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A0712	Inappropriate/Inadequate Shock/Stimulation		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	E2104	Electric Shock	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	E2104	Electric Shock	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F24	Insufficient Health Impact Information	A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
5034	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT2727	Active implant devices/annularrs	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/12/2020	04/12/2020
5035	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
5036	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/01/2021	28/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/01/2021	28/01/2021

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5038	2020	Death	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT1150	Defibrillators	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT1141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT1145	Cardiovascular devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT1233	Surgical	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT12406	Implantable	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT12407	Active implantable	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT1258	Implantable defibrillators	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT12727	Active implant devices/ancillaries	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		
							F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A071301	Failure to Deliver Shock/Stimulation		

CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT2985	Active	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT3001	Implantable metal	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT3006	Implantable inorganic material	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT3007	Implantable ceramic	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT314	Electrically powered	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT321	Long-term surgical invasive	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT449	Generators and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F21	Unexpected Deterioration	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
CT981	Single use	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070910	Undersensing		
				A071301	Failure to Deliver Shock/Stimulation		

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				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F1905	Device Revision or Replacement	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F19	Surgical Intervention	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F1905	Device Revision or Replacement	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F19	Surgical Intervention	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F1905	Device Revision or Replacement	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F19	Surgical Intervention	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F1905	Device Revision or Replacement	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F19	Surgical Intervention	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F1905	Device Revision or Replacement	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F19	Surgical Intervention	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F1905	Device Revision or Replacement	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	2011/2020	2011/2020
				A071302	Inappropriate/Inadequate Shock/Stimulation	2011/2020	2011/2020
				A090801	Signal Artifact/Noise	2011/2020	2011/2020

						F19	Surgical Intervention	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
								A070909	Oversensing	20/11/2020	20/11/2020
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
						F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
								A070909	Oversensing	20/11/2020	20/11/2020
						F19	Surgical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F19	Surgical Intervention	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F19	Surgical Intervention	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F19	Surgical Intervention	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	20/11/2020
								A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F19	Surgical Intervention	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
						F1905	Device Revision or Replacement	A070909	Oversensing	20/11/2020	20/11/2020
								A071302	Inappropriate/Inadequate Shock/Stimulation	20/11/2020	20/11/2020
								A090801	Signal Artifact/Noise	20/11/2020	20/11/2020
5042	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A0712	Pacing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A0712	Pacing Problem		

CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
		F26	No Health Consequences or Impact	A0712	Pacing Problem							
9043	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		

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5044	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		

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						F26	No Health Consequences or Impact	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
5045	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C12985	Active	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C13001	Implantable metal	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C13002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C13006	Implantable inorganic material	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C13007	Implantable ceramic	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C1314	Electrically powered	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C1321	Long-term surgical invasive	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C1449	Generators and associated devices	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C1981	Single use	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
					C1983	Surgical invasive	F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
							E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/inadequate Shock/Stimulation		
5046	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		

5049	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A12	Connection Problem	E3/1/2020	E3/1/2020
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A072201	High Impedance		
									A0712	Pacing Problem		
									A072201	High Impedance		
									A0712	Pacing Problem		
									A072201	High Impedance		
									A070504	Premature Discharge of Battery	13/01/2021	13/01/2021
									A070504	Premature Discharge of Battery	13/01/2021	13/01/2021
									A070504	Premature Discharge of Battery	13/01/2021	13/01/2021
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									A070504	Premature Discharge of Battery	13/01/2021	13/01/2021
									A070504	Premature Discharge of Battery	13/01/2021	13/01/2021

5051	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F12 F19 E2403 F26	Serious Injury/ Illness/ Impairment Surgical Intervention No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504 A070909 A070909	Premature Discharge of Battery Premature Discharge of Battery	13/01/2021 13/01/2021	13/01/2021 13/01/2021
					CT1147	Defibrillators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT1150	Defibrillators	F26 E2403 F26	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT145	Cardiovascular devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT233	Surgical	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT2406	Implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT2407	Active implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT263	Cardiographs and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT2727	Active implant devices/ancillaries	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT2985	Active	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT3001	Implantable metal	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT3002	Implantable synthetic polymer	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT3006	Implantable inorganic material	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT3007	Implantable ceramic	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT314	Electrically powered	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT321	Long-term surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT449	Generators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT981	Single use	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
					CT983	Surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909	Oversensing Oversensing		
5052	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT1150	Defibrillators	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT141	Electrodes/Leads and associated devices	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT145	Cardiovascular devices	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT233	Surgical	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT2406	Implantable	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT2407	Active implantable	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT258	Implantable defibrillators	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT2727	Active implant devices/ancillaries	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT2985	Active	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT3001	Implantable metal	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT3002	Implantable synthetic polymer	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT3006	Implantable inorganic material	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT3007	Implantable ceramic	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT314	Electrically powered	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT321	Long-term surgical invasive	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT449	Generators and associated devices	E2403 F2203	No Clinical Signs, Symptoms or Conditions Imaging Required	A0722 A0722	Impedance Problem Impedance Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		

5053	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1983	Surgical invasive	E2403 F2203	Imaging Required No Clinical Signs, Symptoms or Conditions	A0722 A0722	Impedance Problem Impedance Problem							
					CT1147	Defibrillators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1150	Defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1141	Electrodes/Leads and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1145	Cardiovascular devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1233	Surgical	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT12406	Implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT12407	Active implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT12727	Active implant devices/ancillaries	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT12866	Implantable cardiac electrical stimulators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT12985	Active	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT13001	Implantable metal	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT13002	Implantable synthetic polymer	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT13006	Implantable inorganic material	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT13007	Implantable ceramic	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1314	Electrically powered	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1321	Long-term surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1449	Generators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1981	Single use	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					CT1983	Surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0909 A0909	Unexpected Therapeutic Results Unexpected Therapeutic Results							
					5054	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403 F08	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT11147	Defibrillators and associated devices	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT11150	Defibrillators	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT1141	Electrodes/Leads and associated devices	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT1145	Cardiovascular devices	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT1233	Surgical	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT12406	Implantable	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT12407	Active implantable	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT1258	Implantable defibrillators	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT1263	Cardiographs and associated devices	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
										CT12726	Physiological monitoring/measuring devices	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021
CT12727	Active implant devices/ancillaries	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504						Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021					
CT12750	Implantable cardiac electrical stimulators and associated devices	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504						Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021					
CT12866	Implantable cardiac electrical stimulators	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504						Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021					
CT12985	Active	F19 E2403	Surgical Intervention No Clinical Signs, Symptoms or Conditions	A070504 A070504						Premature Discharge of Battery Premature Discharge of Battery	17/02/2021 17/02/2021	17/02/2021					

							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
5056	2020	All other reportable incidents	4/270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/12/2020	14/12/2020
							F1501	Additional Surgery	A070504	Premature Discharge of Battery	14/12/2020	14/12/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/12/2020	14/12/2020
5057	2020	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

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				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2806	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2104	Electric Shock	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0712	Pacing Problem		

				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT3006	Implantable inorganic material	E2104	Electric Shock	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT3007	Implantable ceramic	E2104	Electric Shock	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT314	Electrically powered	E2104	Electric Shock	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT321	Long-term surgical invasive	E2104	Electric Shock	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			

							CT449	Generators and associated devices	E2104	Electric Shock	A0712	Pacing Problem												
										A071302	Inappropriate/Inadequate Shock/Stimulation													
										A090801	Signal Artifact/Noise													
							E2403		No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem													
										A071302	Inappropriate/Inadequate Shock/Stimulation													
										A090801	Signal Artifact/Noise													
							F08		Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem													
										A071302	Inappropriate/Inadequate Shock/Stimulation													
										A090801	Signal Artifact/Noise													
							F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem													
										A071302	Inappropriate/Inadequate Shock/Stimulation													
										A090801	Signal Artifact/Noise													
							F12		Serious Injury/ Illness/ Impairment	A0712	Pacing Problem													
										A071302	Inappropriate/Inadequate Shock/Stimulation													
										A090801	Signal Artifact/Noise													
							F15		Recognized Device or Procedural Complication	A0712	Pacing Problem													
										A071302	Inappropriate/Inadequate Shock/Stimulation													
										A090801	Signal Artifact/Noise													
							CT981		Single use	E2104	Electric Shock	A0712	Pacing Problem											
											A071302	Inappropriate/Inadequate Shock/Stimulation												
											A090801	Signal Artifact/Noise												
							E2403			No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem												
											A071302	Inappropriate/Inadequate Shock/Stimulation												
											A090801	Signal Artifact/Noise												
							F08			Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem												
											A071302	Inappropriate/Inadequate Shock/Stimulation												
											A090801	Signal Artifact/Noise												
							F10			Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem												
											A071302	Inappropriate/Inadequate Shock/Stimulation												
											A090801	Signal Artifact/Noise												
							F12			Serious Injury/ Illness/ Impairment	A0712	Pacing Problem												
											A071302	Inappropriate/Inadequate Shock/Stimulation												
											A090801	Signal Artifact/Noise												
							F15			Recognized Device or Procedural Complication	A0712	Pacing Problem												
											A071302	Inappropriate/Inadequate Shock/Stimulation												
							CT983			Surgical invasive	E2104	Electric Shock	A0712	Pacing Problem										
												A071302	Inappropriate/Inadequate Shock/Stimulation											
												A090801	Signal Artifact/Noise											
							E2403				No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem											
												A071302	Inappropriate/Inadequate Shock/Stimulation											
												A090801	Signal Artifact/Noise											
							F08				Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem											
												A071302	Inappropriate/Inadequate Shock/Stimulation											
												A090801	Signal Artifact/Noise											
							F10				Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem											
												A071302	Inappropriate/Inadequate Shock/Stimulation											
												A090801	Signal Artifact/Noise											
							F12				Serious Injury/ Illness/ Impairment	A0712	Pacing Problem											
												A071302	Inappropriate/Inadequate Shock/Stimulation											
												A090801	Signal Artifact/Noise											
							F15				Recognized Device or Procedural Complication	A0712	Pacing Problem											
												A071302	Inappropriate/Inadequate Shock/Stimulation											
												A090801	Signal Artifact/Noise											
							5098				2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator				
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT1150	Defibrillators	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT145	Cardiovascular devices	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT233	Surgical	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT2406	Implantable	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT2407	Active implantable	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT258	Implantable defibrillators	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT263	Cardiographs and associated devices	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				
																	F24	Insufficient Health Impact Information	A160601	Premature Elective Replacement Indicator				
																CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A160601	Premature Elective Replacement Indicator			
																	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator				

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					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2406	Implantable	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5063	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		

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					CT314	Electrically powered	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5066	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
5067	2020	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2021	25/01/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/02/2021	20/02/2021

5069	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/01/2021	13/01/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal		
									A070912	Incorrect Interpretation of Signal		
5070	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5071	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5072	2021	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT1150	Defibrillators	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT145	Cardiovascular devices	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT233	Surgical	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2406	Implantable	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2407	Active implantable	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT258	Implantable defibrillators	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2985	Active	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT3001	Implantable metal	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT3006	Implantable inorganic material	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT3007	Implantable ceramic	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT314	Electrically powered	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT321	Long-term surgical invasive	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT449	Generators and associated devices	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT981	Single use	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT983	Surgical invasive	E0602	Cardiac Arrest	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
5073	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		

						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
5074	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT1147	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT141	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT145	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT233	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2406	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2407	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT263	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2726	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2727	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2750	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2866	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2985	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/01/2021	12/01/2021
9076	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/01/2021	26/01/2021
									A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	26/01/2021	26/01/2021
									A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/01/2021	26/01/2021
									A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	26/01/2021	26/01/2021
									A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/01/2021	26/01/2021
									A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	26/01/2021	26/01/2021
									A070504	Premature Discharge of Battery	26/01/2021	26/01/2

						F19	Surgical Intervention	A0705	Battery Problem	26/01/2021	26/01/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/01/2021
								A0705	Battery Problem	26/01/2021	26/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	26/01/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	26/01/2021
								A0705	Battery Problem	26/01/2021	26/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	26/01/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/01/2021
								A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	26/01/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/01/2021
								A070504	Battery Problem	26/01/2021	26/01/2021
							F19	Surgical Intervention	A0705	Premature Discharge of Battery	26/01/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/01/2021
								A0705	Battery Problem	26/01/2021	26/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	26/01/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/01/2021
								A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	26/01/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/01/2021
								A0705	Battery Problem	26/01/2021	26/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	26/01/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/01/2021
								A0705	Battery Problem	26/01/2021	26/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	26/01/2021
5077	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	
5078	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem	
								A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F15	Recognized Device or Procedural Complication	A0709	Device Sensing Problem		
								A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem	
								A070909	Overensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic	A0709	Device Sensing Problem		

			Exposure	A070909	Oversensing		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Oversensing		

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									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
								A070909	Oversensing			
						F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation			
								A0709	Device Sensing Problem			
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem		
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
								A070909	Oversensing			
						F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation			
								A0709	Device Sensing Problem			
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
								A070909	Oversensing			
						F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation			
								A0709	Device Sensing Problem			
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
5079	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
								A070909	Oversensing			
								A090801	Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
								A070101	Failure to Capture			
								A070909	Oversensing			
								A090801	Signal Artifact/Noise			
								A1301	Failure to Read Input Signal			
5080	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	

						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	08/01/2021	08/01/2021	
								A070504	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C12866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C13001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C13006	implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
				C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F19	Surgical Intervention	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/01/2021	08/01/2021	
								A070504	Premature Discharge of Battery	08/01/2021	08/01/2021	
0081	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/01/2021	26/01/2021

2021

All other reportable incidents

35852

Single-chamber implantable defibrillator

CT1010

Cardiovascular physiology analysis/mapping devices

E2403

A0705

26/0

2021

[illegible]

							F19	Surgical Intervention	A0705	Battery Problem	26/01/2021	26/01/2021
5082	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5083	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5084	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F15	Recognized Device or Procedural Complication	A072201	High Impedance		
5085	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT233	Surgical	F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
				A070909	Oversensing		

5086	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A060801	Signal Artifact/Noise		
									A070909	Oversensing		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
								A070909	Oversensing			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A1301	Failure to Read Input Signal			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
5088	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
					CT1150	Defibrillators	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
					CT145	Cardiovascular devices	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
					CT233	Surgical	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021	
									A072202	Low Impedance	13/01/2021	13/01/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
									A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic	A070602	Delayed Charge Time	13/01/2021	13/01/2021	

				exposure	A072202	Low Impedance	13/01/2021	13/01/2021
					A0909	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F1905		Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT2406		Implantable	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0909	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT2407		Active implantable	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0909	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT258		Implantable defibrillators	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0909	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT2727		Active implant devices/ancillaries	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0909	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT2750		Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0909	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
			F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021
					A0909	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
					A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT2866		Implantable cardiac electrical stimulators	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
					A072202	Low Impedance	13/01/2021	13/01/2021

				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT2985	Active	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT3001	Implantable metal	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT3006	Implantable inorganic material	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
CT3007	Implantable ceramic	E2104	Electric Shock	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A090801	Signal Artifact/Noise	13/01/2021	13/01/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time	13/01/2021	13/01/2021
				A072202	Low Impedance	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2021	13/01/2021

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						CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
						E2403	No Clinical Signs, Symptoms or Conditions	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT2727	Active implant devices/ancillaries	F26	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F26	No Health Consequences or Impact	F26	No Health Consequences or Impact	A0705	Battery Problem		
5092	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/02/2021	02/02/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT141	Electrodes/Leads end associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	02/02/2021	02/02/2021	
					F19	Surgical Intervention	A070504	Premature Discharge of Battery	02/02/2021	02/02/2021			

						CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
										A0705	Battery Problem	29/01/2021	29/01/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
										A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
						CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
								F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
										A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
5096	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021	
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	01/03/2021	01/03/2021
										A070504	Premature Discharge of Battery	01/03/2021	01/03/2021

					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT081	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
					CT083	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/03/2021	01/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
									A0705	Battery Problem	01/03/2021	01/03/2021
									A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
5097	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2021	01/03/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	27/01/2021	27/01/2021
									A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	27/01/2021	27/01/2021
									A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021	27/01/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
									A0705	Battery Problem	27/01/2021	27/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
									A0705	Battery Problem	27/01/2021	27/01/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	27/01/2021	27/01/2021
									A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	27/01/2021	27/01/2021
									A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021	27/01/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
									A0705	Battery Problem	27/01/2021	27/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
									A0705	Battery Problem	27/01/2021	27/01/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	27/01/2021	27/01/2021
									A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	27/01/2021	27/01/2021

CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT2407	Active implantable	F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT2726	Physiological monitoring/measuring devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT2866	Implantable cardiac electrical stimulators	F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT3002	Implantable synthetic polymer	F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021
				A0705	Battery Problem	27/01/2021	27/01/2021
				A070504	Premature Discharge of Battery	27/01/2021	27/01/2021

						F19	Surgical Intervention	A0705	Battery Problem	27/01/2021	27/01/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/01/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	27/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/01/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	27/01/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/01/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	27/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/01/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/01/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	27/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	27/01/2021
5098	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT233	Surgical	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT2406	Implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT2985	Active	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
					CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021

9099	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
					CT981	Single use	F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
					CT983	Surgical invasive	F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
					CT1010	Cardiovascular physiology analysis/mapping devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2021	09/03/2021					
							E2401	Insufficient Information	A070909	Overensing							
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
							E2401	Insufficient Information	A070909	Overensing							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
							E2401	Insufficient Information	A070909	Overensing							
					CT1141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT1145	Cardiovascular devices	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT233	Surgical	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT2406	Implantable	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT2407	Active implantable	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT258	Implantable defibrillators	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT263	Cardiographs and associated devices	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT2985	Active	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT3001	Implantable metal	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT3006	Implantable inorganic material	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT3007	Implantable ceramic	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT314	Electrically powered	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT449	Generators and associated devices	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT981	Single use	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					CT983	Surgical invasive	E2401	Insufficient Information	A070909	Overensing							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing							
							F23	Unexpected Medical Intervention	A070909	Overensing							
					9100	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
												F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery							
		F26	No Health Consequences or Impact	A070504						Premature Discharge of Battery							
CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery							
		F26	No Health Consequences or Impact	A070504						Premature Discharge of Battery							
CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery							
		F26	No Health Consequences or Impact	A070504						Premature Discharge of Battery							

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT440	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT681	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5101	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021

5103	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		

						F19	Surgical Intervention	A0705	Battery Problem	15/02/2021	15/02/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2021
								A0705	Battery Problem	15/02/2021	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2021
								A0705	Battery Problem	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/02/2021
								A070504	Premature Discharge of Battery	15/02/2021	15/02/2021
5105	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing	
								A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing	
								A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing	
								A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing	
								A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing	
								A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing	
								A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing	

							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/03/2021	15/03/2021
5108	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
5109	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/01/2021	29/01/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2021	29/01/2021
							F19	Surgical Intervention	A0705	Battery Problem	29/01/2021	29/01/2021

					CT3001	Implantable metal	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT3002	Implantable synthetic polymer	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT3006	Implantable inorganic material	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT3007	Implantable ceramic	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT314	Electrically powered	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT321	Long-term surgical invasive	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT449	Generators and associated devices	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT981	Single use	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
					CT983	Surgical invasive	F26 E2403 F10	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
5111	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/anillaries	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F26 E2104 F10	No Health Consequences or Impact Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F26 E2104	No Health Consequences or Impact Electric Shock	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
5112	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/01/2021	26/01/2021
5113	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT1147	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT141	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT145	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT1233	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT2406	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT2407	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT263	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT2726	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT2727	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
						F19	Surgical Intervention	A0705	Battery Problem	24/02/2021	24/02/2021
								A070504	Premature Discharge of Battery	24/02/2021	24/02/2021
					CT2750	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/02/2021	24/02/2021

5115	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal		

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal		
5116	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT1150	Defibrillators	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT145	Cardiovascular devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT233	Surgical	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2406	Implantable	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2407	Active implantable	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT258	Implantable defibrillators	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT2985	Active	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3001	Implantable metal	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT3007	Implantable ceramic	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT314	Electrically powered	E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A072201	High Impedance		

							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
							E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
							E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F24	Insufficient Health Impact Information	A072201	High Impedance		
							E2401	Insufficient Information	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
									A0705	Battery Problem	16/03/2021	16/03/2021
									A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021	16/03/2021

						F19	Surgical Intervention	A0705	Battery Problem	16/03/2021	16/03/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2021
								A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	16/03/2021
								A0705	Battery Problem	16/03/2021	16/03/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2021
								A0705	Battery Problem	16/03/2021	16/03/2021
							F19	Surgical Intervention	A0705	Battery Problem	16/03/2021
								A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021
								A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							F19	Surgical Intervention	A0705	Battery Problem	16/03/2021
								A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/03/2021
								A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
							F19	Surgical Intervention	A0705	Battery Problem	16/03/2021
								A070504	Premature Discharge of Battery	16/03/2021	16/03/2021
5118	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	
								A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0705	Battery Problem	

						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery					
										A0705	Battery Problem					
										A070504	Premature Discharge of Battery					
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem					
								F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery					
										A0705	Battery Problem					
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery					
								F24	Insufficient Health Impact Information	A0705	Battery Problem					
										A070504	Premature Discharge of Battery					
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery					
								F24	Insufficient Health Impact Information	A0705	Battery Problem					
										A070504	Premature Discharge of Battery					
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem					
								F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery					
										A0705	Battery Problem					
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery					
								F24	Insufficient Health Impact Information	A0705	Battery Problem					
										A070504	Premature Discharge of Battery					
5119	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2021		23/05/2021			
5120	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing						
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation						
							F23	Unexpected Medical Intervention	A070909	Oversensing						
									A071302	Inappropriate/Inadequate Shock/Stimulation						
						CT11147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation						
							F23	Unexpected Medical Intervention	A070909	Oversensing						
									A071302	Inappropriate/Inadequate Shock/Stimulation						
						CT11150	Defibrillators	E2104	Electric Shock	A070909	Oversensing					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation						
									A071302	Inappropriate/Inadequate Shock/Stimulation						

		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT145	Cardiovascular devices	F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

							Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
5121	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT1150	Defibrillators	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT145	Cardiovascular devices	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT233	Surgical	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT2406	Implantable	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT2407	Active implantable	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT258	Implantable defibrillators	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A0712	Pacing Problem		
								A070909	Oversensing			
								A0712	Pacing Problem			

						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
						F0101	Therapeutic Response Decreased	A0712	Pacing Problem			
								A070909	Oversensing			
								A0712	Pacing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT2806	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT2985	Active	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT3001	Implantable metal	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT3006	Implantable inorganic material	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT3007	Implantable ceramic	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT314	Electrically powered	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT449	Generators and associated devices	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT981	Single use	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
					CT983	Surgical invasive	E2401	Insufficient Information	A070909	Oversensing		
								A0712	Pacing Problem			
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A0712	Pacing Problem			
						F0101	Therapeutic Response Decreased	A070909	Oversensing			
								A0712	Pacing Problem			
5122	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A072202	Low Impedance			
								A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A072202	Low Impedance			
								A1301	Failure to Read Input Signal			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
								A072202	Low Impedance			
								A1301	Failure to Read Input Signal			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		

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					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							F1901	Additional Surgery	A090805	Incorrect Measurement	11/02/2021	11/02/2021
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							F1901	Additional Surgery	A090805	Incorrect Measurement	11/02/2021	11/02/2021
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							F1901	Additional Surgery	A090805	Incorrect Measurement	11/02/2021	11/02/2021
					CT981	Single use	F1905	Device Revision or Replacement	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							F1901	Additional Surgery	A090805	Incorrect Measurement	11/02/2021	11/02/2021
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							F1901	Additional Surgery	A090805	Incorrect Measurement	11/02/2021	11/02/2021
							F1905	Device Revision or Replacement	A090805	Incorrect Measurement	11/02/2021	11/02/2021
5129	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F05	Delay to Treatment/ Therapy	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A071201	Failure to Convert Rhythm		

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					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5131	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5132	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Overensing		

				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		P26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		P26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		P26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		P26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		P26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

									A090801 A1301	Signal Artifact/Noise Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F26	No Health Consequences or Impact		A090801 A1301 A070909	Signal Artifact/Noise Failure to Read Input Signal Oversensing		
									A071302 A090801 A1301	Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
5133	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A070910 A0712	Undersensing Pacing Problem		
5134	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070604 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070604 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070604 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070604 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070604 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070604 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
							F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021

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						F08	Hospitalization or Prolonged Hospitalization	A070504 A070602 A0705 A070504 A070602	Premature Discharge of Battery Delayed Charge Time Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021 22/02/2021 22/02/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
						F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
				C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
						F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
				C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
						F1905	Device Revision or Replacement	A0705 A070504 A070602	Battery Problem Premature Discharge of Battery Delayed Charge Time	22/02/2021 22/02/2021 22/02/2021	22/02/2021 22/02/2021 22/02/2021
5135	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT1147	Defibrillators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT1150	Defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT141	Electrodes/Leads and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT145	Cardiovascular devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT233	Surgical	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT2406	Implantable	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT2407	Active implantable	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT258	Implantable defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT283	Cardiographs and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09/02/2021 09/02/2021
					CT2726	Physiological monitoring/measuring devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	09/02/2021 09

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5142	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT321	Long-term surgical invasive	F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021	12/03/2021
					CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1145	Cardiovascular devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT1233	Surgical	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT2406	Implantable	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT12407	Active implantable	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT1258	Implantable defibrillators	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT1263	Cardiographs and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT12726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT12727	Active implant devices/ancillaries	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT12750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							
CT12866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A070504	Premature Discharge of Battery							
				A0908	Incorrect, Inadequate or Imprecise Result or Readings							

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					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/03/2021	05/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/03/2021	05/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/03/2021	05/03/2021
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/03/2021	05/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/03/2021	05/03/2021
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/03/2021	05/03/2021
									A070504	Premature Discharge of Battery	05/03/2021	05/03/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/03/2021	05/03/2021
									A070504	Premature Discharge of Battery	05/03/2021	05/03/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/03/2021	05/03/2021
									A070504	Premature Discharge of Battery	05/03/2021	05/03/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/03/2021	05/03/2021
									A070504	Premature Discharge of Battery	05/03/2021	05/03/2021
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/03/2021	05/03/2021
5144	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT1150	Defibrillators	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT145	Cardiovascular devices	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT233	Surgical	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT2406	Implantable	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT2407	Active implantable	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT258	Implantable defibrillators	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
							E2312	Fatigue	A071201	Failure to Convert Rhythm		
							E2330	Pain	A071201	Failure to Convert Rhythm		
							E233001	Chest Pain	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm		
							F19	Surgical Intervention	A071201	Failure to Convert Rhythm		

5145	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2985	Active	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT3001	Implantable metal	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT3002	Implantable synthetic polymer	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT3006	Implantable inorganic material	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT3007	Implantable ceramic	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT314	Electrically powered	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT321	Long-term surgical invasive	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT449	Generators and associated devices	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT981	Single use	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT983	Surgical invasive	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
					E2312	Fatigue	A071201	Failure to Convert Rhythm				
					E2330	Pain	A071201	Failure to Convert Rhythm				
					E233001	Chest Pain	A071201	Failure to Convert Rhythm				
					F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm				
					F14	Prolonged Episode of Care	A071201	Failure to Convert Rhythm				
					F19	Surgical Intervention	A071201	Failure to Convert Rhythm				
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT133	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

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					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	05/02/2021	05/02/2021
5156	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021	
									A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021	

CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021		
		A0705	Battery Problem	08/02/2021	08/02/2021		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021		
		A0705	Battery Problem	08/02/2021	08/02/2021		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021		
		A0705	Battery Problem	08/02/2021	08/02/2021		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021		
		A0705	Battery Problem	08/02/2021	08/02/2021		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021		
		A0705	Battery Problem	08/02/2021	08/02/2021		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021		
		A0705	Battery Problem	08/02/2021	08/02/2021		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021		
		A0705	Battery Problem	08/02/2021	08/02/2021		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021		
		A0705	Battery Problem	08/02/2021	08/02/2021		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				A0705	Battery Problem	08/02/2021	08/02/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
		A0705	Battery Problem	08/02/2021	08/02/2021		

						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021
						F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021
						F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1903	Device Explanation	A0705	Battery Problem	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2021	08/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	08/02/2021	08/02/2021
						F1903	Device Explanation	A070504	Premature Discharge of Battery	08/02/2021	08/02/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2021	08/02/2021
5157	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2311	Discomfort	A070909	Oversensing	
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		

					CT263	Cardiographs and associated devices	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2311	Discomfort	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5158	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
5159	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021

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						F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
					CT983	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/02/2021	17/02/2021
5160	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
5161	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	

						CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A070909	Oversensing		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
6162	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
								A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
								A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
								A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
								A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
						F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
								A070910	Undersensing	03/03/2021	03/03/2021		
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		
								A071302	Inappropriate/Inadequate Shock/Stimulation	03/03/2021	03/03/2021		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	03/03/2021	03/03/2021	
								A071301	Failure to Deliver Shock/Stimulation	03/03/2021	03/03/2021		

					associated devices	F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/03/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/03/2021	13/03/2021
5164	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT1246	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/03/2021
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/03/2021

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5168	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F1905	Device Revision or Replacement	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F1905	Device Revision or Replacement	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F1905	Device Revision or Replacement	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
									A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
						F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021	
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
									A090801	Signal Artifact/Noise	17/02/2021	17/02/2021

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C1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
F1905	Device Revision or Replacement	A070909	Overensing	17/02/2021	17/02/2021		
		A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021		
		A090801	Signal Artifact/Noise	17/02/2021	17/02/2021		
		A1301	Failure to Read Input Signal	17/02/2021	17/02/2021		
C12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
F1905	Device Revision or Replacement	A070909	Overensing	17/02/2021	17/02/2021		
		A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021		
		A090801	Signal Artifact/Noise	17/02/2021	17/02/2021		
		A1301	Failure to Read Input Signal	17/02/2021	17/02/2021		
C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
F1905	Device Revision or Replacement	A070909	Overensing	17/02/2021	17/02/2021		
		A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021		
		A090801	Signal Artifact/Noise	17/02/2021	17/02/2021		
		A1301	Failure to Read Input Signal	17/02/2021	17/02/2021		
C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
F1905	Device Revision or Replacement	A070909	Overensing	17/02/2021	17/02/2021		
		A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021		
		A090801	Signal Artifact/Noise	17/02/2021	17/02/2021		
		A1301	Failure to Read Input Signal	17/02/2021	17/02/2021		
C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
F1905	Device Revision or Replacement	A070909	Overensing	17/02/2021	17/02/2021		
		A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021		
		A090801	Signal Artifact/Noise	17/02/2021	17/02/2021		
		A1301	Failure to Read Input Signal	17/02/2021	17/02/2021		
C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	17/02/2021	17/02/2021

				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
CT3008	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
				A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	17/02/2021	17/02/2021
				A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
				A090801	Signal Artifact/Noise	17/02/2021	17/02/20

							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
						F08	A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
						F12	A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
						F1905	A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070909	Oversensing	17/02/2021	17/02/2021
							A071302	Inappropriate/Inadequate Shock/Stimulation	17/02/2021	17/02/2021
							A090801	Signal Artifact/Noise	17/02/2021	17/02/2021
							A1301	Failure to Read Input Signal	17/02/2021	17/02/2021
							A070			

						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
										A0705	Battery Problem	23/03/2021	23/03/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
										A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/03/2021	23/03/2021
										A070504	Premature Discharge of Battery	23/03/2021	23/03/2021
								F19	Surgical Intervention	A0705	Battery Problem	23/03/2021	23

CT1150	Defibrillators	P26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0112	Dizziness	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0623	Unspecified Heart Problem	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
		A071302	Undersensing				
CT141	Electrodes/Leads and associated devices	P26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0112	Dizziness	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0623	Unspecified Heart Problem	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
		A071302	Undersensing				
CT145	Cardiovascular devices	P26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0112	Dizziness	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0623	Unspecified Heart Problem	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
		A071302	Undersensing				
CT233	Surgical	P26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0112	Dizziness	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0623	Unspecified Heart Problem	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
		A071302	Undersensing				
CT2408	Implantable	P26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0112	Dizziness	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0623	Unspecified Heart Problem	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
		A071302	Undersensing				
CT2407	Active implantable	P26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0112	Dizziness	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0623	Unspecified Heart Problem	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
		A071302	Undersensing				
CT258	Implantable defibrillators	P26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0112	Dizziness	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		E0623	Unspecified Heart Problem	A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
		A071302	Undersensing				
CT263	Cardiographs and associated devices	E0112	Dizziness	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		

					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
			E0623	Unspecified Heart Problem	A070909	Oversensing		
					A070910	Undersensing		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
			F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E0112	Dizziness		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
		E0623	Unspecified Heart Problem		A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E0112	Dizziness		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
		E0623	Unspecified Heart Problem		A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E0112	Dizziness		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
		E0623	Unspecified Heart Problem		A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E0112	Dizziness		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
		E0623	Unspecified Heart Problem		A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E0112	Dizziness		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
		E0623	Unspecified Heart Problem		A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E0112	Dizziness		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
		E0623	Unspecified Heart Problem		A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E0112	Dizziness		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
		E0623	Unspecified Heart Problem		A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A070909	Oversensing		
					A070910	Undersensing		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E0112	Dizziness	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		E0623	Unspecified Heart Problem	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E0112	Dizziness	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		E0623	Unspecified Heart Problem	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E0112	Dizziness	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		E0623	Unspecified Heart Problem	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E0112	Dizziness	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		E0623	Unspecified Heart Problem	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E0112	Dizziness	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		E0623	Unspecified Heart Problem	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
CT981	Single use	E0112	Dizziness	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		E0623	Unspecified Heart Problem	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
CT983	Surgical invasive	E0112	Dizziness	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		E0623	Unspecified Heart Problem	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Overensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
		F26	No Health Consequences or Impact	A070909 A070910	Overensing Undersensing		

5171	2021	All other reportable incidents	35652	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	23/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2021	22/02/2021

							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
					CT3006	implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2021	21/03/2021
5173	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2007	Fail	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

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								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
						CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
5176	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A070910	Undersensing				
									A0713	Defibrillation/Stimulation Problem				
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
								F26	No Health Consequences or Impact	A0713	Defibrillation/Stimulation Problem			
									A0713	Defibrillation/Stimulation Problem				
5177	2021	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021		
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT1147	Defibrillators and associated devices	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT1150	Defibrillators	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT1141	Electrodes/Leads and associated devices	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT1145	Cardiovascular devices	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT233	Surgical	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT2406	Implantable	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT2407	Active implantable	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT258	Implantable defibrillators	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT263	Cardiographs and associated devices	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT2726	Physiological monitoring/measuring devices	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT2985	Active	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT3001	Implantable metal	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT3002	Implantable synthetic polymer	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT3006	Implantable inorganic material	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT3007	Implantable ceramic	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT314	Electrically powered	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT321	Long-term surgical invasive	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT449	Generators and associated devices	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT981	Single use	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
						CT983	Surgical invasive	E060109	Tachycardia	A0712	Pacing Problem	01/03/2021	01/03/2021	
								E2401	Insufficient Information	A0712	Pacing Problem	01/03/2021	01/03/2021	
								F02	Death	A0712	Pacing Problem	01/03/2021	01/03/2021	
5178	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021		
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/02/2021	19/02/2021	
									A070504	Premature Discharge of Battery	19/02/2021	19/02/2021		

CT1147	Defibrillators and associated devices	F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
CT1150	Defibrillators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT1150	Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
CT141	Electrodes/Leads and associated devices	F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
CT145	Cardiovascular devices			A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT233	Surgical	F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
CT2406	Implantable			A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT2407	Active implantable	F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
CT258	Implantable defibrillators			A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT263	Cardiographs and associated devices	F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
CT2726	Physiological monitoring/measuring devices			A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT2727	Active implant devices/ancillaries	F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021

		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
				A070505	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	19/02/2021	19/02/2021
				A070504	Premature Discharge of Battery	19/02/2021	19/02/2021
		F1903	Device Explanation	A0705	Battery Problem	19/02/2021	19/02/2021</

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						F26	No Health Consequences or Impact	A0908 A070504 A070602 A0908	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings			
					CT149	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact	A070504 A070602 A0908	Premature Discharge of Battery Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings			
5189	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	18/03/2021	18/03/2021	

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
5191	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
							F24	Insufficient Health Impact Information	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A0705	Battery Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
					CT1150	Defibrillators	E2401	Insufficient Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery			
					CT145	Cardiovascular devices	E2401	Insufficient Information	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
							F24	Insufficient Health Impact Information	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT233	Surgical	E2401	Insufficient Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
					CT2406	Implantable	E2401	Insufficient Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
					CT2407	Active implantable	E2401	Insufficient Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
					CT258	Implantable defibrillators	E2401	Insufficient Information	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery			

CT263	Cardiographs and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F24	Insufficient Health Impact Information	A0705	Battery Problem		
CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F24	Insufficient Health Impact Information	A0705	Battery Problem		
CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT2985	Active	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT3001	Implantable metal	E2401	Insufficient Information	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F24	Insufficient Health Impact Information	A0705	Battery Problem		
CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F24	Insufficient Health Impact Information	A0705	Battery Problem		
CT3006	Implantable inorganic material	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT3007	Implantable ceramic	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT314	Electrically powered	E2401	Insufficient Information	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F24	Insufficient Health Impact Information	A0705	Battery Problem		
CT321	Long-term surgical invasive	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT449	Generators and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT981	Single use	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
CT983	Surgical invasive	E2401	Insufficient Information	A070504	Premature Discharge of Battery		
				A0705	Battery Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		

						F22	Unexpected Diagnostic Intervention	A0706	Charging Problem			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Oversensing		
							F22	Unexpected Diagnostic Intervention	A0706	Charging Problem		
									A070909	Oversensing		
									A0706	Charging Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Oversensing		
							F22	Unexpected Diagnostic Intervention	A0706	Charging Problem		
									A070909	Oversensing		
									A0706	Charging Problem		
									A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0706	Charging Problem		
							F22	Unexpected Diagnostic Intervention	A0706	Oversensing		
									A070909	Charging Problem		
									A0706	Oversensing		
5195	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/03/2021	19/03/2021

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						F19	Surgical Intervention	A0705	Battery Problem	15/04/2021	15/04/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/04/2021
								A0705	Battery Problem	15/04/2021	15/04/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/04/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	15/04/2021
								A0705	Premature Discharge of Battery	15/04/2021	15/04/2021
							F19	Surgical Intervention	A070504	Battery Problem	15/04/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/04/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/04/2021
								A0705	Battery Problem	15/04/2021	15/04/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/04/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	15/04/2021
								A0705	Battery Problem	15/04/2021	15/04/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/04/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	15/04/2021
								A070504	Premature Discharge of Battery	15/04/2021	15/04/2021
5200	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
							F26	No Health Consequences or Impact	A070909	Overensing	
5201	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071303	Intermittent Shock/Stimulation	
							E2403	No Clinical Signs, Symptoms or Conditions	A071303	Intermittent Shock/Stimulation	
							F1905	Device Revision or Replacement	A071303	Intermittent Shock/Stimulation	

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						F19	Surgical Intervention	A0705	Battery Problem	25/03/2021	25/03/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
							F19	Surgical Intervention	A0705	Battery Problem	25/03/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
							F19	Surgical Intervention	A0705	Battery Problem	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
							F19	Surgical Intervention	A0705	Battery Problem	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
							F19	Surgical Intervention	A0705	Battery Problem	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
							F19	Surgical Intervention	A0705	Battery Problem	25/03/2021
								A070504	Premature Discharge of Battery	25/03/2021	25/03/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	25/03/2021	25/03/2021
5205	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/03/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021

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					CT314	Electrically powered	F1905 Device Revision or Replacement A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F08 Hospitalization or Prolonged Hospitalization A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F10 Inadequate/Inappropriate Treatment or Diagnostic Exposure A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1903 Device Explanation A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1905 Device Revision or Replacement A070504 Premature Discharge of Battery 14/04/2021 14/04/2021	
					CT321	Long-term surgical invasive	E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F08 Hospitalization or Prolonged Hospitalization A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F10 Inadequate/Inappropriate Treatment or Diagnostic Exposure A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1903 Device Explanation A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1905 Device Revision or Replacement A070504 Premature Discharge of Battery 14/04/2021 14/04/2021	
					CT449	Generators and associated devices	E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F08 Hospitalization or Prolonged Hospitalization A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F10 Inadequate/Inappropriate Treatment or Diagnostic Exposure A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1903 Device Explanation A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1905 Device Revision or Replacement A070504 Premature Discharge of Battery 14/04/2021 14/04/2021	
					CT981	Single use	E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F08 Hospitalization or Prolonged Hospitalization A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F10 Inadequate/Inappropriate Treatment or Diagnostic Exposure A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1903 Device Explanation A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1905 Device Revision or Replacement A070504 Premature Discharge of Battery 14/04/2021 14/04/2021	
					CT983	Surgical invasive	E2403 No Clinical Signs, Symptoms or Conditions A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F08 Hospitalization or Prolonged Hospitalization A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F10 Inadequate/Inappropriate Treatment or Diagnostic Exposure A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1903 Device Explanation A070504 Premature Discharge of Battery 14/04/2021 14/04/2021 F1905 Device Revision or Replacement A070504 Premature Discharge of Battery 14/04/2021 14/04/2021	
5212	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401 Insufficient Information A070101 Failure to Capture Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070101 Failure to Capture Oversensing F15 Recognized Device or Procedural Complication A070101 Failure to Capture Oversensing	
5213	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT1147	Defibrillators and associated devices	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT1150	Defibrillators	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT141	Electrodes/Leads and associated devices	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT145	Cardiovascular devices	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT233	Surgical	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT2406	Implantable	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT2407	Active implantable	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT258	Implantable defibrillators	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT263	Cardiographs and associated devices	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT2726	Physiological monitoring/measuring devices	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT2727	Active implant devices/ancillaries	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT2866	Implantable cardiac electrical stimulators	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT2985	Active	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT3001	Implantable metal	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT3002	Implantable synthetic polymer	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	
					CT3006	Implantable inorganic material	F26 No Health Consequences or Impact A070900 Oversensing E2401 Insufficient Information A070900 Oversensing E2403 No Clinical Signs, Symptoms or Conditions A070900 Oversensing	

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/04/2021	01/04/2021
5218	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	12/04/2021	12/04/2021

						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
										A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F08	Hospitalization or Prolonged Hospitalization			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
						F1905	Device Revision or Replacement			A0705	Battery Problem	12/04/2021	12/04/2021
										A070504	Premature Discharge of Battery	12/04/2021	12/04/2021
5219	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						F19	Surgical Intervention			A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						F19	Surgical Intervention			A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						F19	Surgical Intervention			A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0705	Battery Problem	20/04/2021	20/04/2021
										A070504	Premature Discharge of Battery	20/04/2021	20/04/2021

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							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
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									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
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									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
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							F26	No Health Consequences or Impact	A070909	Oversensing			
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							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A071302	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302				

					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator			
5223	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/04/2021		07/04/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	07/04/2021		07/04/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/04/2021		07/04/2021
5224	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A23	Use of Device Problem			
							F08	Hospitalization or Prolonged Hospitalization	A23	Use of Device Problem			
							F1901	Additional Surgery	A23	Use of Device Problem			
5225	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021		24/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/05/2021		24/05/2021
									A0705	Battery Problem	24/05/2021		24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021		24/05/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021		24/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/05/2021		24/

							F19	Surgical Intervention	A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
									A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F19	Surgical Intervention	A0705	Battery Problem	24/05/2021	24/05/2021
									A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
5226	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021	28/04/2021
									A070504	Premature Discharge of Battery	28/04/2021	28/04/2021

						F19	Surgical Intervention	A0705	Battery Problem	28/04/2021	28/04/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2021
								A0705	Battery Problem	28/04/2021	28/04/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	28/04/2021
								A0705	Battery Problem	28/04/2021	28/04/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/04/2021
								A0705	Battery Problem	28/04/2021	28/04/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	28/04/2021
								A0705	Battery Problem	28/04/2021	28/04/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
							F19	Surgical Intervention	A0705	Battery Problem	28/04/2021
								A070504	Premature Discharge of Battery	28/04/2021	28/04/2021
3227	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0133	Stroke/CVA	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E020201	Anxiety	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F14	Prolonged Episode of Care	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E0133	Stroke/CVA	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E020201	Anxiety	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F14	Prolonged Episode of Care	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E0133	Stroke/CVA	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E020201	Anxiety	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F14	Prolonged Episode of Care	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E0133	Stroke/CVA	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E020201	Anxiety	A070909	Oversensing		

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C12727	Active implant devices/ancillaries	F14	Prolonged Episode of Care	A070909	Overensing			
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E0133	Stroke/CVA	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E020201	Anxiety	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
C12750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F14	Prolonged Episode of Care	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E0133	Stroke/CVA	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E020201	Anxiety	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
C12866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F14	Prolonged Episode of Care	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E0133	Stroke/CVA	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
C12985	Active	E020201	Anxiety	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F14	Prolonged Episode of Care	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
C13001	Implantable metal	E0133	Stroke/CVA	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E020201	Anxiety	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F14	Prolonged Episode of Care	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
C13002	Implantable synthetic polymer	F23	Unexpected Medical Intervention	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E0133	Stroke/CVA	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E020201	Anxiety	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
C13008	Implantable inorganic material	F14	Prolonged Episode of Care	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E0133	Stroke/CVA	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E020201	Anxiety	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
C13007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F14	Prolonged Episode of Care	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E0133	Stroke/CVA	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			

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					C7983	Surgical invasive	F26 E2403 F26	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070909 A070909 A070909	Oversensing Oversensing Oversensing		
5231	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F08 F1903 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explication Device Revision or Replacement	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	14/04/2021 14/04/2021 14/04/2021 14/04/2021	14/04/2021 14/04/2021 14/04/2021 14/04/2021
5232	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT1150	Defibrillators	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT1141	Electrodes/Leads and associated devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT145	Cardiovascular devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT233	Surgical	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT2406	Implantable	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT2407	Active implantable	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT258	Implantable defibrillators	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT12727	Active implant devices/ancillaries	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT2985	Active	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT3001	Implantable metal	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT3002	Implantable synthetic polymer	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT3006	implantable inorganic material	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT3007	Implantable ceramic	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT314	Electrically powered	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT321	Long-term surgical invasive	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT449	Generators and associated devices	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT981	Single use	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT983	Surgical invasive	E2403 F1905	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
5233	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT1147	Defibrillators and associated devices	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT1150	Defibrillators	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT1141	Electrodes/Leads and associated devices	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT145	Cardiovascular devices	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT233	Surgical	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT2406	Implantable	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT2407	Active implantable	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT258	Implantable defibrillators	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT263	Cardiographs and associated devices	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT2726	Physiological monitoring/measuring devices	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT12727	Active implant devices/ancillaries	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT12750	Implantable cardiac electrical stimulators and associated devices	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT2866	Implantable cardiac electrical stimulators	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT2985	Active	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT3001	Implantable metal	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT3002	Implantable synthetic polymer	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT3006	implantable inorganic material	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT3007	Implantable ceramic	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		
					CT314	Electrically powered	E060102 F1905	Atrial Fibrillation Device Revision or Replacement	A1201 A1201	Blocked Connection Blocked Connection		

					CT321	Long-term surgical invasive	E060102	Atrial Fibrillation	A1201	Blocked Connection		
							F1905	Device Revision or Replacement	A1201	Blocked Connection		
					CT449	Generators and associated devices	E060102	Atrial Fibrillation	A1201	Blocked Connection		
							F1905	Device Revision or Replacement	A1201	Blocked Connection		
					CT981	Single use	E060102	Atrial Fibrillation	A1201	Blocked Connection		
							F1905	Device Revision or Replacement	A1201	Blocked Connection		
					CT983	Surgical invasive	E060102	Atrial Fibrillation	A1201	Blocked Connection		
							F1905	Device Revision or Replacement	A1201	Blocked Connection		
5234	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
5235	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5236	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021	
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021	
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021	
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021	
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021	
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
					CT1147	Defibrillators and associated devices	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021	
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021	
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021	
								A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021	
								A072201	High Impedance	06/05/2021	06/05/2021	
						F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021	

				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT1150	Defibrillators	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT141	Electrodes/Leads and associated devices	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT145	Cardiovascular devices	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT233	Surgical	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT2406	Implantable	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021

CT2407	Active implantable	F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021		
		A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021		
		A072201	High Impedance	06/05/2021	06/05/2021		
F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021		
		A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021		
		A072201	High Impedance	06/05/2021	06/05/2021		
F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021		
		A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021		
		A072201	High Impedance	06/05/2021	06/05/2021		
CT258	Implantable defibrillators	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021		
		A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021		
		A072201	High Impedance	06/05/2021	06/05/2021		
CT263	Cardiographs and associated devices	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021		
		A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021		
		A072201	High Impedance	06/05/2021	06/05/2021		
CT2726	Physiological monitoring/measuring devices	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021		
		A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021		
		A072201	High Impedance	06/05/2021	06/05/2021		
CT2727	Active implant devices/ancillaries	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021

				F1001	Absence of Treatment	A072201	High Impedance	06/05/2021	06/05/2021
						A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				F19	Surgical Intervention	A072201	High Impedance	06/05/2021	06/05/2021
						A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E060102	Atrial Fibrillation			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
CT2866	Implantable cardiac electrical stimulators	E060102	Atrial Fibrillation			A072201	High Impedance	06/05/2021	06/05/2021
						A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
CT2985	Active	E060102	Atrial Fibrillation			A072201	High Impedance	06/05/2021	06/05/2021
						A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation			A010402	Migration	06/05/2021	06/05/2021
						A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
						A072201	High Impedance	06/05/2021	06/05/2021

				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT3006	Implantable inorganic material	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT3007	Implantable ceramic	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT314	Electrically powered	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT321	Long-term surgical invasive	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F05	Delay to Treatment/ Therapy	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F1001	Absence of Treatment	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		F19	Surgical Intervention	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
CT449	Generators and associated devices	E060102	Atrial Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E060110	Ventricular Fibrillation	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021
		E0611	Heart Failure/Congestive Heart Failure	A010402	Migration	06/05/2021	06/05/2021
				A071201	Failure to Convert Rhythm	06/05/2021	06/05/2021
				A072201	High Impedance	06/05/2021	06/05/2021

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						CT298	Implantable defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance			
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
						CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance			
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
								F26	No Health Consequences or Impact	A072201	High Impedance			
5241	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
					CT1145	Cardiovascular devices	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
					CT1233	Surgical	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
					CT2406	Implantable	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
					CT2407	Active implantable	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
							F26	No Health Consequences or Impact	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Overensing				
								A071302	Inappropriate/Inadequate Shock/Stimulation					

5242	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2985	Active	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing	
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
5242	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	

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							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/04/2021	15/04/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	15/04/2021	15/04/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	15/04/2021	15/04/2021	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/04/2021	15/04/2021	
5244	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement	16/04/2021	16/04/2021	
							F1901	Additional Surgery	A090805	Incorrect Measurement	16/04/2021	16/04/2021	
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
5245	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021	

						F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
						F19	Surgical Intervention	A070504	Premature Discharge of Battery	19/05/2021	19/05/2021
5246	2021	All other reportable incidents	57265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5247	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
								A070909	Oversensing		
						F15	Recognized Device or Procedural Complication	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
								A070909	Oversensing		
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F15	Recognized Device or Procedural Complication	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
								A070909	Oversensing		
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F15	Recognized Device or Procedural Complication	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
								A070909	Oversensing		
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F15	Recognized Device or Procedural Complication	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
								A070909	Oversensing		
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F15	Recognized Device or Procedural Complication	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
								A070909	Oversensing		
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								A070909	Oversensing		
						F15	Recognized Device or Procedural Complication	A0709	Device Sensing Problem		

		F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT2407	Active implantable	F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT258	Implantable defibrillators	F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT2727	Active implant devices/ancillaries	F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT2985	Active	F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT3006	Implantable inorganic material	F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT314	Electrically powered	F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0709	Device Sensing Problem		
CT321	Long-term surgical invasive	F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A0709	Device Sensing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0709	Device Sensing Problem		

							F26	No Health Consequences or Impact	A070909 A0709 A070909	Oversensing Device Sensing Problem Oversensing			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909	Device Sensing Problem Oversensing			
							F15	Recognized Device or Procedural Complication	A0709 A070909	Device Sensing Problem Oversensing			
							F26	No Health Consequences or Impact	A0709 A070909	Device Sensing Problem Oversensing			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909	Device Sensing Problem Oversensing			
							F15	Recognized Device or Procedural Complication	A0709 A070909	Device Sensing Problem Oversensing			
							F26	No Health Consequences or Impact	A0709 A070909	Device Sensing Problem Oversensing			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909	Device Sensing Problem Oversensing			
							F15	Recognized Device or Procedural Complication	A0709 A070909	Device Sensing Problem Oversensing			
							F26	No Health Consequences or Impact	A0709 A070909	Device Sensing Problem Oversensing			
5248	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
							F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem			

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
						F1905	Device Revision or Replacement	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A25	No Apparent Adverse Event	16/03/2021
						F1905	Device Revision or Replacement	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A25	No Apparent Adverse Event	16/03/2021
						F1905	Device Revision or Replacement	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A25	No Apparent Adverse Event	16/03/2021
						F1905	Device Revision or Replacement	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A25	No Apparent Adverse Event	16/03/2021
						F1905	Device Revision or Replacement	A25	No Apparent Adverse Event	16/03/2021	16/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT145	Cardiovascular devices	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT233	Surgical	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT2406	Implantable	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT2407	Active implantable	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT2985	Active	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021
						E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT3006	Implantable inorganic material	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT3007	Implantable ceramic	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT314	Electrically powered	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT449	Generators and associated devices	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT981	Single use	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
					CT983	Surgical invasive	E2401	Insufficient Information	A16	Protective Measures Problem	24/03/2021
						F1905	Device Revision or Replacement	A16	Protective Measures Problem	24/03/2021	24/03/2021
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A070909	Oversensing		
								A0712	Pacing Problem		
								A070909	Oversensing		
								A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A0712	Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	

		F26	No Health Consequences or Impact	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT2407	Active implantable	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT258	Implantable defibrillators	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT263	Cardiographs and associated devices	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT2726	Physiological monitoring/measuring devices	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT2727	Active implant devices/ancillaries	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT2866	Implantable cardiac electrical stimulators	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT2985	Active	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT3001	Implantable metal	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT3002	Implantable synthetic polymer	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT3006	Implantable inorganic material	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT3007	Implantable ceramic	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT314	Electrically powered	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT321	Long-term surgical invasive	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
		E0602	Cardiac Arrest	A070909	Oversensing		
				A0712	Pacing Problem		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A0712	Pacing Problem		
CT449	Generators and associated devices	E060101	Asystole	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		

								E0602	Cardiac Arrest	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Pacing Problem		
										A0712	Oversensing		
						CT981	Single use			A0712	Pacing Problem		
								E060101	Asystole	A070909	Oversensing		
										A0712	Pacing Problem		
								E0602	Cardiac Arrest	A070909	Oversensing		
										A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A070909	Oversensing		
										A0712	Pacing Problem		
						CT983	Surgical invasive			A070909	Oversensing		
								E060101	Asystole	A070909	Pacing Problem		
										A0712	Oversensing		
								E0602	Cardiac Arrest	A070909	Pacing Problem		
										A0712	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
										A0712	Pacing Problem		
5255	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	23/03/2021	23/03/2021	
5256	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2021	23/04/2021	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/04/2021	23/04/2021	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/04/2021	23/04/2021	
5257	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021	
									A0705	Battery Problem	07/06/2021	07/06/2021	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021	
									A070504	Premature Discharge of Battery	07/06/2021	07/06/2021	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	07/06/2021	07/06/2021	
									A070504	Premature Discharge of Battery	07/06/2021	07/06/2021	
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021	
									A070504	Premature Discharge of Battery	07/06/2021	07/06/2021	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	07/06/2021	07/06/2021	
									A070504	Premature Discharge of Battery	07/06/2021	07/06/2021	
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021	
									A070504	Premature Discharge of Battery	07/06/2021	07/06/2021	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	07/06/2021	07/06/2021	
									A070504	Premature Discharge of Battery	07/06/2021	07/06/2021	

			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem
			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem
			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					A0705	Premature Discharge of Battery	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					A0705	Premature Discharge of Battery	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
CT314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
			F1905	Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021
					A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
					A0705	Battery Problem	07/06/2021	07/06/2021
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
								Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
								No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
								Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	07/06/2021	07/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
								Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
					C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
								No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/06/2021	07/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
								Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	07/06/2021	07/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
								Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
								Device Revision or Replacement	A070504	Premature Discharge of Battery	07/06/2021	07/06/2021
								Device Revision or Replacement	A0705	Battery Problem	07/06/2021	07/06/2021
5258	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
								Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
								Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
								Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
								Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
								Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
								Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
								No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021

		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT12965	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
				A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/06/2021	04/06/2021
				A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/06/2021	04/06/2021

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CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
		F26	No Health Consequences or Impact	A23	Use of Device Problem		
				A070909	Oversensing		
				A070910	Undersensing		
				A23	Use of Device Problem		

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A23 A070909 A070910 A23	Use of Device Problem Oversensing Undersensing Use of Device Problem		
							F26	No Health Consequences or Impact	A070909 A070910 A23	Oversensing Undersensing Use of Device Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A23	Oversensing Undersensing Use of Device Problem		
							F26	No Health Consequences or Impact	A070909 A070910 A23	Oversensing Undersensing Use of Device Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A23	Oversensing Undersensing Use of Device Problem		
							F26	No Health Consequences or Impact	A070909 A070910 A23	Oversensing Undersensing Use of Device Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A23	Oversensing Undersensing Use of Device Problem		
							F26	No Health Consequences or Impact	A070909 A070910 A23	Oversensing Undersensing Use of Device Problem		
3264	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021

						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021	26/07/2021
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/07/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/07/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/07/2021
5285	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2985	Active	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
							F26	No Health Consequences or Impact	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing	

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		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		

					CT314	Electrically powered	F1905 E2403 F1903 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Device Explanation Device Revision or Replacement	A160601 A160601 A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT321	Long-term surgical invasive	E2403 F1903 F1905	No Clinical Signs, Symptoms or Conditions Device Explanation Device Revision or Replacement	A160601 A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT449	Generators and associated devices	E2403 F1903 F1905	No Clinical Signs, Symptoms or Conditions Device Explanation Device Revision or Replacement	A160601 A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT981	Single use	E2403 F1903 F1905	No Clinical Signs, Symptoms or Conditions Device Explanation Device Revision or Replacement	A160601 A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
					CT983	Surgical invasive	E2403 F1903 F1905	No Clinical Signs, Symptoms or Conditions Device Explanation Device Revision or Replacement	A160601 A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator Premature Elective Replacement Indicator		
5273	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT1147	Defibrillators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT1150	Defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT141	Electrodes/Leads and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT145	Cardiovascular devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT233	Surgical	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT2406	Implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT2407	Active implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT263	Cardiographs and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT2726	Physiological monitoring/measuring devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT2727	Active implant devices/ancillaries	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT2866	Implantable cardiac electrical stimulators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT2985	Active	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT3001	Implantable metal	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT3002	Implantable synthetic polymer	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT3006	Implantable inorganic material	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT3007	Implantable ceramic	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT314	Electrically powered	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT321	Long-term surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT449	Generators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT981	Single use	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
					CT983	Surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	13/05/2021	13/05/2021
5274	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Battery Problem Premature Discharge of Battery Battery Problem Premature Discharge of Battery	25/05/2021	25/05/2021
					CT1147	Defibrillators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	25/05/2021	25/05/2021
					CT1150	Defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0705 A070504	Battery Problem Premature Discharge of Battery Battery Problem Premature Discharge of Battery	25/05/2021	25/05/2021
					CT141	Electrodes/Leads and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0705 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery Battery Problem	25/05/2021	25/05/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/05/2021	25/05/2021

				A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070503	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A070503	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A070503	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A070503	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A070503	Battery Problem	25/05/2021	25/05/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/05/2021	25/05/2021
				A0705	Battery Problem	25/05/2021	25/05

5275	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/05/2021	25/05/2021
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F1905	Device Revision or Replacement	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/05/2021	25/05/2021
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F1905	Device Revision or Replacement	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/05/2021	25/05/2021
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F1905	Device Revision or Replacement	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/05/2021	25/05/2021
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F1905	Device Revision or Replacement	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/05/2021	25/05/2021
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					F1905	Device Revision or Replacement	A0705	Battery Problem	25/05/2021	25/05/2021		
							A070504	Premature Discharge of Battery	25/05/2021	25/05/2021		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic	A070909	Oversensing		

					CT2407	Active implantable	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT258	Implantable defibrillators	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT263	Cardiographs and associated devices	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT12726	Physiological monitoring/measuring devices	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT12727	Active implant devices/ancillaries	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT12750	Implantable cardiac electrical stimulators and associated devices	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT12866	Implantable cardiac electrical stimulators	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT2985	Active	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT3001	Implantable metal	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT3002	Implantable synthetic polymer	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT3006	Implantable inorganic material	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT3007	Implantable ceramic	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT1314	Electrically powered	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT321	Long-term surgical invasive	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT449	Generators and associated devices	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT981	Single use	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
					CT983	Surgical invasive	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A160601 A160601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	31/03/2021 31/03/2021	31/03/2021 31/03/2021
5278	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F10 F1905 F26	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure Device Revision or Replacement No Health Consequences or Impact	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	30/04/2021 30/04/2021 30/04/2021 30/04/2021	30/04/2021 30/04/2021 30/04/2021 30/04/2021
5279	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F1905 F26	No Clinical Signs, Symptoms or Conditions Device Revision or Replacement No Health Consequences or Impact	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	31/03/2021 31/03/2021 31/03/2021	31/03/2021 31/03/2021 31/03/2021
5280	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F08 F10	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021
					CT1147	Defibrillators and associated devices	F1905 E2403 F08 F10	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021 12/08/2021
					CT1150	Defibrillators	F1905 E2403 F08 F10	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021 12/08/2021
					CT141	Electrodes/leads and associated devices	F1905 E2403 F08 F10	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021 12/08/2021
					CT145	Cardiovascular devices	F1905 E2403 F08 F10	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021 12/08/2021
					CT233	Surgical	F1905 E2403 F08 F10	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021 12/08/2021
					CT2406	Implantable	F1905 E2403 F08 F10	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021 12/08/2021
					CT2407	Active implantable	F1905 E2403 F08 F10	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021 12/08/2021
					CT258	Implantable defibrillators	F1905 E2403 F08 F10	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021 12/08/2021
					CT263	Cardiographs and associated devices	F1905 E2403 F08	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/08/2021 12/08/2021 12/08/2021	12/08/2021 12/08/2021 12/08/2021

						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT2407	Active implantable	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT258	Implantable defibrillators	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT263	Cardiographs and associated devices	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT2726	Physiological monitoring/measuring devices	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT2727	Active implant devices/ancillaries	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT2866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT2985	Active	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT3001	Implantable metal	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT3002	Implantable synthetic polymer	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT3006	Implantable inorganic material	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT3007	Implantable ceramic	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT314	Electrically powered	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT321	Long-term surgical invasive	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT449	Generators and associated devices	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT981	Single use	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
					CT983	Surgical invasive	E011903	Syncope/Fainting	A0203	Defective Device	
						F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device		
						F21	Unexpected Deterioration	A0203	Defective Device		
5282	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
						F26	No Health Consequences or Impact	A070909	Oversensing		

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT314	Electrically powered	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5283	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		

6284	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator			F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A072201	High Impedance		
									A0508	Noise, Audible		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A072201	High Impedance		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
									A0705	Battery Problem	26/05/2021	26/05/2021
									A070504	Premature Discharge of Battery	26/05/2021	26/05/2021

						F1905	Device Revision or Replacement	A0705	Battery Problem	26/05/2021	26/05/2021
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A0705	Battery Problem	26/05/2021	26/05/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/05/2021	26/05/2021
5285	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F11	Non-Serious Injury/ Illness/ Impairment	A072201	High Impedance		
5286	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem	
						F11	Non-Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
5287	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/04/2022
						F1903	Device Explanation	A070909	Oversensing	01/04/2022	01/04/2022
						F26	No Health Consequences or Impact	A070909	Oversensing	01/04/2022	01/04/2022
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/04/2022	01/04/2022
						F1903	Device Explanation	A070909	Oversensing	01/04/2022	01/04/2022
						F26	No Health Consequences or Impact	A070909	Oversensing	01/04/2022	01/04/2022
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/04/2022	01/04/2022
						F1903	Device Explanation	A070909	Oversensing	01/04/2022	01/04/2022
						F26	No Health Consequences or Impact	A070909	Oversensing	01/04/2022	01/04/2022
				CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/04/2022	01/04/2022
						F1903	Device Explanation	A070909	Oversensing	01/04/2022	01/04/2022
						F26	No Health Consequences or Impact	A070909	Oversensing	01/04/2022	01/04/2022
				CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/04/2022	01/04/2022
						F1903	Device Explanation	A070909	Oversensing	01/04/2022	01/04/2022
						F26	No Health Consequences or Impact	A070909	Oversensing	01/04/2022	01/04/2022
				CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/04/2022	01/04/2022
						F1903	Device Explanation	A070909	Oversensing	01/04/2022	01/04/2022
						F26	No Health Consequences or Impact	A070909	Oversensing	01/04/2022	01/04/2022
				CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/04/2022	01/04/2022
						F1903	Device Explanation	A070909	Oversensing	01/04/2022	01/04/2022
						F26	No Health Consequences or Impact	A070909	Oversensing	01/04/2022	01/04/2022
				CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/04/2022	01/04/2022
						F1903	Device Explanation	A070909	Oversensing	01/04/2022	01/04/2022

[illegible]

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[illegible]

[illegible]

[illegible]

[illegible]

CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT2965	Active	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A070909	Oversensing		

5295	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing								
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation								
									A070909	Oversensing								
									A071302	Inappropriate/Inadequate Shock/Stimulation								
							E2104	Electric Shock	A070909	Oversensing								
									A071302	Inappropriate/Inadequate Shock/Stimulation								
									A090801	Signal Artifact/Noise								
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing								
									A071302	Inappropriate/Inadequate Shock/Stimulation								
									A090801	Signal Artifact/Noise								
							F26	No Health Consequences or Impact	A070909	Oversensing								
									A071302	Inappropriate/Inadequate Shock/Stimulation								
									A090801	Signal Artifact/Noise								
							CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing						
									A071302	Inappropriate/Inadequate Shock/Stimulation								
									A090801	Signal Artifact/Noise								
									E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing						
										A071302	Inappropriate/Inadequate Shock/Stimulation							
										A090801	Signal Artifact/Noise							
									F26	No Health Consequences or Impact	A070909	Oversensing						
										A071302	Inappropriate/Inadequate Shock/Stimulation							
										A090801	Signal Artifact/Noise							
									CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing				
											A071302	Inappropriate/Inadequate Shock/Stimulation						
											A090801	Signal Artifact/Noise						
											E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
												A071302	Inappropriate/Inadequate Shock/Stimulation					
												A090801	Signal Artifact/Noise					
											F26	No Health Consequences or Impact	A070909	Oversensing				
												A071302	Inappropriate/Inadequate Shock/Stimulation					
												A090801	Signal Artifact/Noise					
											CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											F26	No Health Consequences or Impact	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											F26	No Health Consequences or Impact	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											F26	No Health Consequences or Impact	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											F26	No Health Consequences or Impact	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											F26	No Health Consequences or Impact	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											F26	No Health Consequences or Impact	A070909	Oversensing				
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
													A071302	Inappropriate/Inadequate Shock/Stimulation				
													A090801	Signal Artifact/Noise				
											E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				

				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2965	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

5296	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
							F26	No Health Consequences or Impact	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
							E2104	Electric Shock	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
					F26	No Health Consequences or Impact	A070909	Oversensing											
							A071302	Inappropriate/Inadequate Shock/Stimulation											
							A090801	Signal Artifact/Noise											
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
							F26	No Health Consequences or Impact	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
							CT981	Single use	E2104	Electric Shock	A070909	Oversensing							
											A071302	Inappropriate/Inadequate Shock/Stimulation							
											A090801	Signal Artifact/Noise							
					E2403	No Clinical Signs, Symptoms or Conditions			A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
					F26	No Health Consequences or Impact			A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
					CT983	Surgical invasive			E2104	Electric Shock	A070909	Oversensing							
											A071302	Inappropriate/Inadequate Shock/Stimulation							
											A090801	Signal Artifact/Noise							
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
							F26	No Health Consequences or Impact	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
							5296	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021
																A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
																A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
					F08	Hospitalization or Prolonged Hospitalization								A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
					F12	Serious Injury/ Illness/ Impairment								A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
					F19	Surgical Intervention								A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
					F1905	Device Revision or Replacement						A070909	Oversensing	18/05/2021	18/05/2021				
												A090801	Signal Artifact/Noise	18/05/2021	18/05/2021				
												A1301	Failure to Read Input Signal	18/05/2021	18/05/2021				
					CT1147	Defibrillators and associated devices						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
					F1905	Device Revision or Replacement						A070909	Oversensing	18/05/2021	18/05/2021				
												A090801	Signal Artifact/Noise	18/05/2021	18/05/2021				
												A1301	Failure to Read Input Signal	18/05/2021	18/05/2021				
					CT1150	Defibrillators						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
					F1905	Device Revision or Replacement						A070909	Oversensing	18/05/2021	18/05/2021				
												A090801	Signal Artifact/Noise	18/05/2021	18/05/2021				
												A1301	Failure to Read Input Signal	18/05/2021	18/05/2021				
					CT141	Electrodes/Leads and associated devices						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
												F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021		
														A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
														A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
					F1905	Device Revision or Replacement						A070909	Oversensing	18/05/2021	18/05/2021				
		A090801	Signal Artifact/Noise	18/05/2021	18/05/2021														
		A1301	Failure to Read Input Signal	18/05/2021	18/05/2021														

CT145	Cardiovascular devices	F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
				A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
				A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
		F19	Surgical Intervention	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
				A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
				A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
				A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
				A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
				A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
		F19	Surgical Intervention	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
				A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
F1905	Device Revision or Replacement	A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
		A070909	Overensing	18/05/2021	18/05/2021		
		A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
	F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021	
			A090801	Signal Artifact/Noise	18/05/2021	18/05/2021	
			A1301	Failure to Read Input Signal	18/05/2021	18/05/2021	
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
F19		Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021	
			A090801	Signal Artifact/Noise	18/05/2021	18/05/2021	
			A1301	Failure to Read Input Signal	18/05/2021	18/05/2021	
F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021		
		A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
		A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
	F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021	
			A090801	Signal Artifact/Noise	18/05/2021	18/05/2021	
			A1301	Failure to Read Input Signal	18/05/2021	18/05/2021	
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
F19		Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021	
			A090801	Signal Artifact/Noise	18/05/2021	18/05/2021	
			A1301	Failure to Read Input Signal	18/05/2021	18/05/2021	
F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021		
		A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
		A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
	F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021	
			A090801	Signal Artifact/Noise	18/05/2021	18/05/2021	
			A1301	Failure to Read Input Signal	18/05/2021	18/05/2021	
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
F19		Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021	
			A090801	Signal Artifact/Noise	18/05/2021	18/05/2021	
			A1301	Failure to Read Input Signal	18/05/2021	18/05/2021	
F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021		
		A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
		A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
	F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021	
			A090801	Signal Artifact/Noise	18/05/2021	18/05/2021	
			A1301	Failure to Read Input Signal	18/05/2021	18/05/2021	
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
F19		Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021	
			A090801	Signal Artifact/Noise	18/05/2021	18/05/2021	
			A1301	Failure to Read Input Signal	18/05/2021	18/05/2021	
F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021		
		A090801	Signal Artifact/Noise	18/05/2021	18/05/2021		
		A1301	Failure to Read Input Signal	18/05/2021	18/05/2021		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021

				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
C12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
C12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
C12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
C12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Oversensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021

CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F12	Serious Injury/ Illness/ Impairment	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F19	Surgical Intervention	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021
		F1905	Device Revision or Replacement	A070909	Overensing	18/05/2021	18/05/2021
				A090801	Signal Artifact/Noise	18/05/2021	18/05/2021
				A1301	Failure to Read Input Signal	18/05/2021	18/05/2021

					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Failure to Read Input Signal Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021 18/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F12	Serious Injury/ Illness/ Impairment	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F19	Surgical Intervention	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
					CT181	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F12	Serious Injury/ Illness/ Impairment	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F19	Surgical Intervention	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
					CT183	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F12	Serious Injury/ Illness/ Impairment	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F19	Surgical Intervention	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	18/05/2021 18/05/2021 18/05/2021	18/05/2021 18/05/2021 18/05/2021
5297	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

						CT981	Single use	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
						CT983	Surgical invasive	F26 E2403	No Health Consequences or Impact No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
5298	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators		E2403 P1901 P1905	No Clinical Signs, Symptoms or Conditions Additional Surgery Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	11/05/2021 11/05/2021 11/05/2021	11/05/2021
5299	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A160503	Inappropriate or Unexpected Reset		
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A160503	Inappropriate or Unexpected Reset		
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT233	Surgical		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT2406	Implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT2726	Physiological monitoring/measuring devices		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A160503	Inappropriate or Unexpected Reset		
					CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A160503	Inappropriate or Unexpected Reset		
					CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A160503	Failure to Charge Inappropriate or Unexpected Reset		
								F23	Unexpected Medical Intervention	A070603	Failure to Charge		
					CT314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070603 A070603	Inappropriate or Unexpected Reset Failure to Charge		
								F23	Unexpected Medical Intervention	A160503	Inappropriate or Unexpected Reset		
										A070603	Failure to Charge		
					CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A160503 A070603	Inappropriate or Unexpected Reset Failure to Charge		

									A160503	Inappropriate or Unexpected Reset		
							F23	Unexpected Medical Intervention	A070603	Failure to Charge		
									A160503	Inappropriate or Unexpected Reset		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge		
							F23	Unexpected Medical Intervention	A070603	Inappropriate or Unexpected Reset		
									A160503	Failure to Charge		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Inappropriate or Unexpected Reset		
							F23	Unexpected Medical Intervention	A160503	Failure to Charge		
									A070603	Inappropriate or Unexpected Reset		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge		
							F23	Unexpected Medical Intervention	A160503	Inappropriate or Unexpected Reset		
									A070603	Failure to Charge		
5300	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
5301	2021	All other reportable incidents	45852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
					CT1150	Defibrillators	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
					CT145	Cardiovascular devices	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
					CT233	Surgical	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
					CT2406	Implantable	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
					CT2407	Active implantable	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
					CT258	Implantable defibrillators	E2401	Insufficient Information	A0705	Battery Problem	12/05/2021	12/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/05/2021	12/05/2021
							F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021

CT263	Cardiographs and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A0705	Battery Problem	12/05/2021	12/05/2021
CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A0705	Battery Problem	12/05/2021	12/05/2021
CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
CT2985	Active	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
CT3001	Implantable metal	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
CT3006	Implantable inorganic material	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
CT3007	Implantable ceramic	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
CT314	Electrically powered	E2401	Insufficient Information	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
				A0705	Battery Problem	12/05/2021	12/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021
		F19	Surgical Intervention	A070504	Premature Discharge of Battery	12/05/2021	12/05/2021

					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
5304	2021	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0602	Cardiac Arrest	A070101	Failure to Capture		
									A070909	Oversensing		
									A070910	Undersensing		
									A071206	Pacing Asynchronously		
							E0611	Heart Failure/Congestive Heart Failure	A070101	Failure to Capture		
									A070909	Oversensing		
									A070910	Undersensing		
									A071206	Pacing Asynchronously		
							F02	Death	A070101	Failure to Capture		
									A070909	Oversensing		
									A070910	Undersensing		
									A071206	Pacing Asynchronously		
5305	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/05/2021	24/05/2021

5306	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/05/2021	24/05/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
					CT1147	Defibrillators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021

						F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
								A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
S307	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing	
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F15	Recognized Device or Procedural Complication	A070909	Oversensing		
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F15	Recognized Device or Procedural Complication	A070909	Oversensing		
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing	
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F15	Recognized Device or Procedural Complication	A070909	Oversensing		
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								A070910	Undersensing		

		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F15	Recognized Device or Procedural Complication	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2985	Active	E2104	Electric Shock	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F15	Recognized Device or Procedural Complication	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
				A070910	Undersensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				

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CT233	Surgical	F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021	29/06/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Battery Problem	29/06/2021	29/06/2021
		F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021

						F1903	Device Explanation	A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
								A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT321	Long-term surgical invasive		A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
						F1903	Device Explanation	A0705	Battery Problem	29/06/2021	29/06/2021
								A070504	Premature Discharge of Battery	29/06/2021	29/06/2021
6311	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
						CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem

						F1905	Device Revision or Replacement	A0705	Battery Problem	24/06/2021	24/06/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	24/06/2021
								A070504	Premature Discharge of Battery	24/06/2021	24/06/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2021
								A0705	Battery Problem	24/06/2021	24/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/06/2021
5312	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	
								A072201	High Impedance		
							F26	No Health Consequences or Impact	A0508	Noise, Audible	
								A072201	High Impedance		
5313	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A0712	Pacing Problem		
							F11	Non-Serious Injury/ Illness/ Impairment	A070909	Overensing	
								A0712	Pacing Problem		
5314	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Overensing	

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
5315	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		

5316	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT981	Single use	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	25/05/2021	25/05/2021
									A072201	High Impedance	25/05/2021	25/05/2021
									A12	Connection Problem	25/05/2021	25/05/2021
									A1204	Failure to Disconnect	25/05/2021	25/05/2021
									A1205	Loose or Intermittent Connection	25/05/2021	25/05/2021
							F1901	Additional Surgery	A070909	Oversensing	25/05/2021	25/05/2021
									A072201	High Impedance	25/05/2021	25/05/2021
									A12	Connection Problem	25/05/2021	25/05/2021
									A1204	Failure to Disconnect	25/05/2021	25/05/2021
									A1205	Loose or Intermittent Connection	25/05/2021	25/05/2021
							F1905	Device Revision or Replacement	A070909	Oversensing	25/05/2021	25/05/2021
									A072201	High Impedance	25/05/2021	25/05/2021
									A12	Connection Problem	25/05/2021	25/05/2021
									A1204	Failure to Disconnect	25/05/2021	25/05/2021
									A1205	Loose or Intermittent Connection	25/05/2021	25/05/2021
5317	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
					CT1150	Defibrillators			A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
					CT145	Cardiovascular devices			A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT233	Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
					CT2406	Implantable			A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
					CT258	Implantable defibrillators			A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
					CT2750	Implantable cardiac electrical stimulators and associated devices			A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021

					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/06/2021	23/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/06/2021	23/06/2021
									A070504	Premature Discharge of Battery	23/06/2021	23/06/2021
5318	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/10/2021	07/10/2021
									A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/10/2021	07/10/2021
									A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/10/2021	07/10/2021
									A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/10/2021	07/10/2021
									A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/10/2021	07/10/2021

CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT2407	Active implantable	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT3007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021
				A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
				A0705	Battery Problem	07/10/2021	07/10/2021

							F1905	Device Revision or Replacement	A0705	Battery Problem	07/10/2021	07/10/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/10/2021	07/10/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/10/2021	07/10/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/10/2021	07/10/2021
5319	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/10/2021	07/10/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions				
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions				
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions				
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions				
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions				
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions				
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions				
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions				
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions				
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions				
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions				
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions				
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions				
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions				
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions				
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions				
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions				
5320	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A072201	High Impedance		
									A12	Connection Problem		
						F08	Hospitalization or Prolonged Hospitalization		A070101	Failure to Capture		
									A072201	High Impedance		
									A12	Connection Problem		
						F12	Serious Injury/ Illness/ Impairment		A070101	Failure to Capture		
									A072201	High Impedance		
									A12	Connection Problem		
						F1905	Device Revision or Replacement		A070101	Failure to Capture		
									A072201	High Impedance		
									A12	Connection Problem		
5321	2021	All other reportable incidents	57265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
							E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
					CT1150	Defibrillators	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
							E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
					CT141	Electrodes/Leads and associated devices	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
							E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
					CT145	Cardiovascular devices	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
							E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
					CT233	Surgical	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
							E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
					CT2406	Implantable	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
							E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
					CT2407	Active implantable	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
							E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
					CT258	Implantable defibrillators	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
							E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
					CT2727	Active implant devices/ancillaries	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		

						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT2750	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT2866	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT2985	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT3001	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT3002	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT3006	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT3007	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT314	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT321	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT449	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT981	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
					CT983	E2308	Deformity/ Disfigurement	A0722	Impedance Problem		
						E2311	Discomfort	A0722	Impedance Problem		
						F11	Non-Serious Injury/ Illness/ Impairment	A0722	Impedance Problem		
5322	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT141	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT145	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT1233	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT2406	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT2407	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT2727	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT2750	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT2866	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT2985	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT3001	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT3002	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT3006	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT3007	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT314	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/06/2021	04/06/2021
5323	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
									A070102	High Capture Threshold		
									A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
									A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070102	High Capture Threshold		
									A072201	High Impedance		
									A1601	Device Alarm System		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
									A070102	High Capture Threshold		
									A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
									A070102	High Capture Threshold		
									A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
									A070102	High Capture Threshold		
									A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
									A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070102	High Capture Threshold		
									A072201	High Impedance		
									A1601	Device Alarm System		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
									A070102	High Capture Threshold		
									A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
									A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070102	High Capture Threshold		
									A072201	High Impedance		
									A1601	Device Alarm System		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
									A070102	High Capture Threshold		
									A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
									A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070102	High Capture Threshold		
									A072201	High Impedance		
									A1601	Device Alarm System		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
									A070102	High Capture Threshold		
									A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
									A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A070102	High Capture Threshold		
									A072201	High Impedance		
									A1601	Device Alarm System		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
									A070102	High Capture Threshold		
									A072201	High Impedance		

						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System							
						F26		No Health Consequences or Impact	A070102	High Capture Threshold								
									A072201	High Impedance								
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System							
										A070102	High Capture Threshold							
								F26	No Health Consequences or Impact	A072201	High Impedance							
						A1601	Device Alarm System											
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold							
										A072201	High Impedance							
								F26	No Health Consequences or Impact	A1601	Device Alarm System							
						A070102	High Capture Threshold											
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
										A1601	Device Alarm System							
								F26	No Health Consequences or Impact	A070102	High Capture Threshold							
						A072201	High Impedance											
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System							
										A070102	High Capture Threshold							
								F26	No Health Consequences or Impact	A072201	High Impedance							
						A1601	Device Alarm System											
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold							
										A072201	High Impedance							
								F26	No Health Consequences or Impact	A1601	Device Alarm System							
						A070102	High Capture Threshold											
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
										A1601	Device Alarm System							
								F26	No Health Consequences or Impact	A070102	High Capture Threshold							
						A072201	High Impedance											
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System							
										A070102	High Capture Threshold							
								F26	No Health Consequences or Impact	A072201	High Impedance							
						A1601	Device Alarm System											
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold							
										A072201	High Impedance							
								F26	No Health Consequences or Impact	A1601	Device Alarm System							
						A070102	High Capture Threshold											
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
										A1601	Device Alarm System							
								F26	No Health Consequences or Impact	A070102	High Capture Threshold							
						A072201	High Impedance											
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System							
										A070102	High Capture Threshold							
								F26	No Health Consequences or Impact	A072201	High Impedance							
						A1601	Device Alarm System											
						5324	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021		
													F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021		
													F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
															F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
													F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
															F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
													F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
															F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
													F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
															F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
													F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
															F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery
													F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021
											CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/07/2021	14/07/2021

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CT145	Cardiovascular devices	E2007	Fall	A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
CT233	Surgical	F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
		F19	Surgical Intervention	A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT2406	Implantable	F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT2407	Active implantable	E2007	Fall	A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
CT258	Implantable defibrillators	F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT263	Cardiographs and associated devices	E2007	Fall	A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
CT2726	Physiological monitoring/measuring devices	F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
		F19	Surgical Intervention	A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2007	Fall	A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021

CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
		E2007	Fail	A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A0203	Defective Device	26/05/2021	26/05/2021
				A010402	Migration	26/05/2021	26/05/2021
		F12	Serious Injury/ Illness/ Impairment	A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		E2007	Fail	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT2985	Active	F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT3001	Implantable metal	F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		E2007	Fail	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT3002	Implantable synthetic polymer	E2007	Fail	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		E2007	Fail	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT3006	Implantable inorganic material	F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		E2007	Fail	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT3007	Implantable ceramic	F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT314	Electrically powered	E2007	Fail	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		E2007	Fail	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT321	Long-term surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
CT449	Generators and associated devices	F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		E2007	Fail	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F19	Surgical Intervention	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021
		F1905	Device Revision or Replacement	A010402	Migration	26/05/2021	26/05/2021
				A0203	Defective Device	26/05/2021	26/05/2021

						F1905	Device Revision or Replacement	A0203 A010402 A0203	Defective Device Migration Defective Device	26/05/2021 26/05/2021 26/05/2021	26/05/2021 26/05/2021 26/05/2021	
				C1981	Single use	E2007	Fail	A010402 A0203	Migration Defective Device	26/05/2021 26/05/2021	26/05/2021 26/05/2021	
						F08	Hospitalization or Prolonged Hospitalization	A010402 A0203	Migration Defective Device	26/05/2021 26/05/2021	26/05/2021 26/05/2021	
						F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021	
						F19	Surgical Intervention	A0203 A010402	Defective Device Migration	26/05/2021 26/05/2021	26/05/2021 26/05/2021	
						F1905	Device Revision or Replacement	A0203 A010402	Defective Device Migration	26/05/2021 26/05/2021	26/05/2021 26/05/2021	
				C1983	Surgical invasive	E2007	Fail	A0203 A010402	Defective Device Migration	26/05/2021 26/05/2021	26/05/2021 26/05/2021	
						F08	Hospitalization or Prolonged Hospitalization	A010402 A0203	Migration Defective Device	26/05/2021 26/05/2021	26/05/2021 26/05/2021	
						F12	Serious Injury/ Illness/ Impairment	A010402	Migration	26/05/2021	26/05/2021	
						F19	Surgical Intervention	A010402 A0203	Migration Defective Device	26/05/2021 26/05/2021	26/05/2021 26/05/2021	
						F1905	Device Revision or Replacement	A010402 A0203	Defective Device Migration	26/05/2021 26/05/2021	26/05/2021 26/05/2021	
5326	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021
							Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
				CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/07/2021	12/07/2021	

						CT981	Single use	E2403 F08	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/07/2021 12/07/2021 12/07/2021	12/07/2021 12/07/2021 12/07/2021
						CT983	Surgical invasive	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explanation	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	12/07/2021 12/07/2021 12/07/2021	12/07/2021 12/07/2021 12/07/2021
5327	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1147	Defibrillators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT1150	Defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT141	Electrodes/Leads and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT145	Cardiovascular devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT1233	Surgical	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT12406	Implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT12407	Active implantable	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT1258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT12727	Active implant devices/ancillaries	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT12750	Implantable cardiac electrical stimulators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT12866	Implantable cardiac electrical stimulators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT12985	Active	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT3001	Implantable metal	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT3002	Implantable synthetic polymer	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT3006	Implantable inorganic material	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT3007	Implantable ceramic	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT314	Electrically powered	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT321	Long-term surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT449	Generators and associated devices	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT981	Single use	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021
						CT983	Surgical invasive	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A0705 A070504 A070504	Battery Problem Premature Discharge of Battery Battery Problem	10/08/2021 10/08/2021 10/08/2021	10/08/2021 10/08/2021 10/08/2021

5328	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/08/2021	10/08/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/06/2021	28/06/2021					
					5329	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/08/2021	03/06/2021
											F02	Death	A070504	Premature Discharge of Battery	13/06/2021	03/06/2021	
					5330	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/07/2021	22/07/2021
												F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/07/2021	22/07/2021
		F1905	Device Revision or Replacement	A0705						Battery Problem	22/07/2021	22/07/2021					
				A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705						Battery Problem	22/07/2021	22/07/2021					
		F08	Hospitalization or Prolonged Hospitalization	A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
		F1905	Device Revision or Replacement	A0705						Battery Problem	22/07/2021	22/07/2021					
				A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705						Battery Problem	22/07/2021	22/07/2021					
		F08	Hospitalization or Prolonged Hospitalization	A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
		F1905	Device Revision or Replacement	A0705						Battery Problem	22/07/2021	22/07/2021					
				A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705						Battery Problem	22/07/2021	22/07/2021					
		F08	Hospitalization or Prolonged Hospitalization	A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
		F1905	Device Revision or Replacement	A0705						Battery Problem	22/07/2021	22/07/2021					
				A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705						Battery Problem	22/07/2021	22/07/2021					
		F08	Hospitalization or Prolonged Hospitalization	A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
		F1905	Device Revision or Replacement	A0705						Battery Problem	22/07/2021	22/07/2021					
				A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705						Battery Problem	22/07/2021	22/07/2021					
		F08	Hospitalization or Prolonged Hospitalization	A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
		F1905	Device Revision or Replacement	A0705						Battery Problem	22/07/2021	22/07/2021					
				A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705						Battery Problem	22/07/2021	22/07/2021					
				A070504						Premature Discharge of Battery	22/07/2021	22/07/2021					

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							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	2207/2021	2207/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	2207/2021	2207/2021
									A070504	Premature Discharge of Battery	2207/2021	2207/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2207/2021	2207/2021
									A070504	Premature Discharge of Battery	2207/2021	2207/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2207/2021	2207/2021
									A070504	Premature Discharge of Battery	2207/2021	2207/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	2207/2021	2207/2021
									A070504	Premature Discharge of Battery	2207/2021	2207/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2207/2021	2207/2021
									A070504	Premature Discharge of Battery	2207/2021	2207/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2207/2021	2207/2021
									A070504	Premature Discharge of Battery	2207/2021	2207/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	2207/2021	2207/2021
									A070504	Premature Discharge of Battery	2207/2021	2207/2021
5331	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT1150	Defibrillators	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT1141	Electrodes/leads and associated devices	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT1145	Cardiovascular devices	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT233	Surgical	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT2406	Implantable	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT2407	Active implantable	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT258	Implantable defibrillators	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT263	Cardiographs and associated devices	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT2726	Physiological monitoring/measuring devices	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021
							F24	Insufficient Health Impact Information	A0705	Battery Problem	1107/2021	1107/2021
									A070504	Premature Discharge of Battery	1107/2021	1107/2021

						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery									
						A070504	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery									
						A070504	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery									
						A070504	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
						A0705	Battery Problem											
						A070504	Premature Discharge of Battery											
						3335	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070900	Oversensing		

5343	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																	

CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F19	Surgical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

					CT983	Surgical Invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
5345	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							F19	Surgical Intervention	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
					CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							F19	Surgical Intervention	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
					CT1150	Defibrillators	E0601	Arrhythmia	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							F19	Surgical Intervention	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
					CT1141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							F19	Surgical Intervention	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
							F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021		03/06/2021
									A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021
									A090801	Signal Artifact/Noise	03/06/2021		03/06/2021
CT1145	Cardiovascular devices	E0601	Arrhythmia	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		F19	Surgical Intervention	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
CT1233	Surgical	E0601	Arrhythmia	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		F19	Surgical Intervention	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
CT2406	Implantable	E0601	Arrhythmia	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		F19	Surgical Intervention	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
		F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					
CT2407	Active implantable	E0601	Arrhythmia	A0711	Interrogation Problem	03/06/2021		03/06/2021					
				A071201	Failure to Convert Rhythm	03/06/2021		03/06/2021					
				A090801	Signal Artifact/Noise	03/06/2021		03/06/2021					

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[illegible]

								A071201	Failure to Convert Rhythm	03/06/2021	03/06/2021
								A090801	Signal Artifact/Noise	03/06/2021	03/06/2021
						E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021	03/06/2021
								A071201	Failure to Convert Rhythm	03/06/2021	03/06/2021
						F19	Surgical Intervention	A090801	Signal Artifact/Noise	03/06/2021	03/06/2021
								A0711	Interrogation Problem	03/06/2021	03/06/2021
								A071201	Failure to Convert Rhythm	03/06/2021	03/06/2021
								A090801	Signal Artifact/Noise	03/06/2021	03/06/2021
						F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021	03/06/2021
								A071201	Failure to Convert Rhythm	03/06/2021	03/06/2021
								A090801	Signal Artifact/Noise	03/06/2021	03/06/2021
					CT983	Surgical invasive		A0711	Interrogation Problem	03/06/2021	03/06/2021
								A071201	Failure to Convert Rhythm	03/06/2021	03/06/2021
								A090801	Signal Artifact/Noise	03/06/2021	03/06/2021
						E0623	Unspecified Heart Problem	A0711	Interrogation Problem	03/06/2021	03/06/2021
								A071201	Failure to Convert Rhythm	03/06/2021	03/06/2021
								A090801	Signal Artifact/Noise	03/06/2021	03/06/2021
						F19	Surgical Intervention	A0711	Interrogation Problem	03/06/2021	03/06/2021
								A071201	Failure to Convert Rhythm	03/06/2021	03/06/2021
								A090801	Signal Artifact/Noise	03/06/2021	03/06/2021
						F1905	Device Revision or Replacement	A0711	Interrogation Problem	03/06/2021	03/06/2021
								A071201	Failure to Convert Rhythm	03/06/2021	03/06/2021
								A090801	Signal Artifact/Noise	03/06/2021	03/06/2021
5346	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
5347	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact	A070909	Oversensing		

6349	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2406	Implantable	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2407	Active implantable	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2985	Active	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3001	Implantable metal	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT314	Electrically powered	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT981	Single use	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A0709	Device Sensing Problem		
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
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		E2104	Electric Shock	A0709	Device Sensing Problem							
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		E2104	Electric Shock	A0709	Device Sensing Problem							
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		E2104	Electric Shock	A0709	Device Sensing Problem							
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		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
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		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation							
		E2104	Electric Shock	A0709	Device Sensing Problem							
		F26	No Health Consequences or Impact									

					CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
5350	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		

						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
5351	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
								A0705	Battery Problem	08/07/2021	08/07/2021	
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
								A0705	Battery Problem	08/07/2021	08/07/2021	
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/07/2021	08/07/2021	
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
								A0705	Battery Problem	08/07/2021	08/07/2021	
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/07/2021	08/07/2021	
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/07/2021	08/07/2021	
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/07/2021	08/07/2021	
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
						F1905	Device Revision or Replacement	A0705	Battery Problem	08/07/2021	08/07/2021	
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
								A070504	Premature Discharge of Battery	08/07/2021	08/07/2021	

CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A0705	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A0705	Premature Discharge of Battery	08/07/2021	08/07/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	08/07/2021	08/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/07/2021	08/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/07/2021	08/07/2021

		F1905	Device Revision or Replacement	A0705	Battery Problem	07/07/2021	07/07/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT2727	Active implant devices/ancillaries	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT2985	Active	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT3006	Implantable inorganic material	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT321	Long-term surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
CT983	Surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021
				A0705	Battery Problem	07/07/2021	07/07/2021
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2021	07/07/2021

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3357	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
									A0705	Battery Problem	10/09/2021	10/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/09/2021	10/09/2021
									A070504	Premature Discharge of Battery	10/09/2021	10/09/2021
					CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		

CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Premature Discharge of Battery	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Premature Discharge of Battery	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Premature Discharge of Battery	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Premature Discharge of Battery	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Premature Discharge of Battery	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Premature Discharge of Battery	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
				A160503	Inappropriate or Unexpected Reset	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Premature Discharge of Battery	2/04/2021	2/04/2021
				A070504	Premature Discharge of Battery	2/04/2021	2/04/2021
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	2/04/2021	2/04/2021

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						F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
								A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
								A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
								A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
3364	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021
								A070504	Premature Discharge of Battery		15/09/2021
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021

			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
CT2407	Active implantable		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2021	15/09/2021
					A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
CT2726	Physiological monitoring/measuring devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT2727	Active implant devices/ancillaries		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT2750	Implantable cardiac electrical stimulators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT2985	Active		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT3001	Implantable metal		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT3002	Implantable synthetic polymer		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT3006	Implantable inorganic material		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021
CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2021	15/09/2021
					A0705	Battery Problem	15/09/2021	15/09/2021

5367	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation							
						F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation								
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					5368	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem	18/05/2021	18/05/2021
											F1905	Device Revision or Replacement	A24	No Apparent Device Problem	18/05/2021	18/05/2021	
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
		F1905	Device Revision or Replacement	A24						No Apparent Device Problem	18/05/2021	18/05/2021					
										F26	No Health Consequences or Impact	A24	No Apparent Device Problem	18/05/2021	18/05/2021		

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					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/06/2021	25/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/06/2021	25/06/2021
									A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/06/2021	25/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/06/2021	25/06/2021
									A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/06/2021	25/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/06/2021	25/06/2021
									A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/06/2021	25/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/06/2021	25/06/2021
									A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/06/2021	25/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/06/2021	25/06/2021
									A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/06/2021	25/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/06/2021	25/06/2021
									A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/06/2021	25/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/06/2021	25/06/2021
									A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	25/06/2021	25/06/2021
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
							F1905	Device Revision or Replacement	A0705	Battery Problem	25/06/2021	25/06/2021
									A070504	Premature Discharge of Battery	25/06/2021	25/06/2021
5373	2021	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060101	Asystole	A070909	Oversensing	25/06/2021	25/06/2021
							E0623	Unspecified Heart Problem	A0712	Pacing Problem		
							F05	Delay to Treatment/ Therapy	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A070909	Oversensing		
					CT1150	Defibrillators	E060101	Asystole	A070909	Oversensing		
							E0623	Unspecified Heart Problem	A0712	Pacing Problem		
							F05	Delay to Treatment/ Therapy	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A070909	Oversensing		
					CT1141	Electrodes/Leads and associated devices	E060101	Asystole	A0712	Pacing Problem		
							E0623	Unspecified Heart Problem	A070909	Oversensing		
							F05	Delay to Treatment/ Therapy	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A0712	Pacing Problem		
					CT1145	Cardiovascular devices	E060101	Asystole	A070909	Oversensing		
							E0623	Unspecified Heart Problem	A0712	Pacing Problem		
							F05	Delay to Treatment/ Therapy	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A070909	Oversensing		
					CT1233	Surgical	E060101	Asystole	A070909	Oversensing		
							E0623	Unspecified Heart Problem	A0712	Pacing Problem		
							F05	Delay to Treatment/ Therapy	A070909	Oversensing		
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem		
									A070909	Oversensing		
					CT2406	Implantable	E060101	Asystole	A070909	Oversensing		

				A07012	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
		F05	Delay to Treatment/ Therapy	A0712	Pacing Problem			
				A070909	Overensing			
		F15	Recognized Device or Procedural Complication	A0712	Pacing Problem			
				A070909	Overensing			
CT2407	Active implantable	E060101	Asystole	A0712	Pacing Problem			
				A070909	Overensing			
		E0623	Unspecified Heart Problem	A0712	Pacing Problem			
				A070909	Overensing			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT258	Implantable defibrillators	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT2727	Active implant devices/ancillaries	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT2750	Implantable cardiac electrical stimulators and associated devices	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT2866	Implantable cardiac electrical stimulators	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT2985	Active	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT3001	Implantable metal	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT3002	Implantable synthetic polymer	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT3006	Implantable inorganic material	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT3007	Implantable ceramic	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
		E0623	Unspecified Heart Problem	A070909	Overensing			
				A0712	Pacing Problem			
		F05	Delay to Treatment/ Therapy	A070909	Overensing			
				A0712	Pacing Problem			
		F15	Recognized Device or Procedural Complication	A070909	Overensing			
				A0712	Pacing Problem			
CT314	Electrically powered	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			

							E0623	Unspecified Heart Problem	A070909	Oversensing		
							F05	Delay to Treatment/ Therapy	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A0712	Pacing Problem		
						CT321		Long-term surgical invasive	A070909	Oversensing		
							E060101	Asystole	A0712	Pacing Problem		
							E0623	Unspecified Heart Problem	A070909	Oversensing		
							F05	Delay to Treatment/ Therapy	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A0712	Pacing Problem		
						CT449		Generators and associated devices	A070909	Oversensing		
							E060101	Asystole	A0712	Pacing Problem		
							E0623	Unspecified Heart Problem	A070909	Oversensing		
							F05	Delay to Treatment/ Therapy	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A0712	Pacing Problem		
						CT981		Single use	A070909	Oversensing		
							E060101	Asystole	A0712	Pacing Problem		
							E0623	Unspecified Heart Problem	A070909	Oversensing		
							F05	Delay to Treatment/ Therapy	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A0712	Pacing Problem		
						CT983		Surgical invasive	A070909	Oversensing		
							E060101	Asystole	A0712	Pacing Problem		
							E0623	Unspecified Heart Problem	A070909	Oversensing		
							F05	Delay to Treatment/ Therapy	A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A0712	Pacing Problem		
5374	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/07/2021	01/07/2021
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/07/2021	01/07/2021
5375	2021	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0119	Loss of Consciousness	A0709	Device Sensing Problem	27/06/2021	27/06/2021
									A070910	Undersensing	27/06/2021	27/06/2021
									A071301	Failure to Deliver Shock/Stimulation	27/06/2021	27/06/2021
							E060109	Tachycardia	A0709	Device Sensing Problem	27/06/2021	27/06/2021
									A070910	Undersensing	27/06/2021	27/06/2021
									A071301	Failure to Deliver Shock/Stimulation	27/06/2021	27/06/2021
							E060110	Ventricular Fibrillation	A0709	Device Sensing Problem	27/06/2021	27/06/2021
									A070910	Undersensing	27/06/2021	27/06/2021
									A071301	Failure to Deliver Shock/Stimulation	27/06/2021	27/06/2021
							E0602	Cardiac Arrest	A0709	Device Sensing Problem	27/06/2021	27/06/2021
									A070910	Undersensing	27/06/2021	27/06/2021
									A071301	Failure to Deliver Shock/Stimulation	27/06/2021	27/06/2021
							F02	Death	A0709	Device Sensing Problem	27/06/2021	27/06/2021
									A070910	Undersensing	27/06/2021	27/06/2021
									A071301	Failure to Deliver Shock/Stimulation	27/06/2021	27/06/2021
							F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem	27/06/2021	27/06/2021
									A070910	Undersensing	27/06/2021	27/06/2021
									A071301	Failure to Deliver Shock/Stimulation	27/06/2021	27/06/2021
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	27/06/2021	27/06/2021
									A070910	Undersensing	27/06/2021	27/06/2021
									A071301	Failure to Deliver Shock/Stimulation	27/06/2021	27/06/2021
5376	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						CT1147		Defibrillators and associated devices	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						CT1150		Defibrillators	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						CT141		Electrodes/Leads and associated devices	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						CT145		Cardiovascular devices	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						CT233		Surgical	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
						CT2406		Implantable	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery							
									A070504	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery							
									A070504	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
									A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
									A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
									A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem							
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery							
									A070504	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
									A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery							
									A070504	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
									A0705	Battery Problem							
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
									A0705	Battery Problem							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
									A0705	Battery Problem							
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
									A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A0705	Battery Problem							
									A070504	Premature Discharge of Battery							
					5377	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
												F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
														A070909	Oversensing		
														A090801	Signal Artifact/Noise		
										CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
												F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
														A070909	Oversensing		
														A090801	Signal Artifact/Noise		
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
												F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
														A070909	Oversensing		
														A090801	Signal Artifact/Noise		
										CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
												F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
														A070909	Oversensing		
														A090801	Signal Artifact/Noise		
										CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
												F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
														A070909	Oversensing		
														A090801	Signal Artifact/Noise		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A090801	Signal Artifact/Noise Oversensing		
								F13	Misdiagnosis/ Misclassification	A070909 A090801	Oversensing Signal Artifact/Noise		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A090801	Oversensing Signal Artifact/Noise		
								F13	Misdiagnosis/ Misclassification	A070909 A090801	Oversensing Signal Artifact/Noise		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A090801	Oversensing Signal Artifact/Noise		
								F13	Misdiagnosis/ Misclassification	A070909 A090801	Oversensing Signal Artifact/Noise		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A090801	Oversensing Signal Artifact/Noise		
								F13	Misdiagnosis/ Misclassification	A070909 A090801	Oversensing Signal Artifact/Noise		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A090801	Oversensing Signal Artifact/Noise		
								F13	Misdiagnosis/ Misclassification	A070909 A090801	Oversensing Signal Artifact/Noise		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A090801	Oversensing Signal Artifact/Noise		
								F13	Misdiagnosis/ Misclassification	A070909 A090801	Oversensing Signal Artifact/Noise		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A090801	Oversensing Signal Artifact/Noise		
								F13	Misdiagnosis/ Misclassification	A070909 A090801	Oversensing Signal Artifact/Noise		
5379	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712	Oversensing Pacing Problem			
								F26	No Health Consequences or Impact	A070909 A0712	Oversensing Pacing Problem		
5380	2021				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070803 A09	Failure to Power Up Output Problem			
5381	2021	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090803 A070504	False Negative Result Premature Discharge of Battery	27/05/2021		27/05/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/05/2021	27/05/2021
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	27/05/2021	27/05/2021
								F19	Surgical Intervention	A070504	Premature Discharge of Battery	27/05/2021	27/05/2021
5382	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset			
								F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset		
5383	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A26	Insufficient Device Problem Information			
								F24	Insufficient Health Impact Information	A26	Insufficient Device Problem Information		
5384	2021	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201 A090801	High Impedance Signal Artifact/Noise			
								F15	Recognized Device or Procedural Complication	A072201 A090801	High Impedance Signal Artifact/Noise		
								F2203	Imaging Required	A072201 A090801	High Impedance Signal Artifact/Noise		
5385	2021	All other reportable incidents			CT258	Implantable defibrillators	E0601	Arrhythmia	A070910 A071201	Undersensing Failure to Convert Rhythm			
								E2403	No Clinical Signs, Symptoms or Conditions	A070910 A071201	Undersensing Failure to Convert Rhythm		
								F08	Hospitalization or Prolonged Hospitalization	A070910 A071201	Undersensing Failure to Convert Rhythm		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A071201	Undersensing Failure to Convert Rhythm		
5386	2021	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/11/2021		27/11/2021
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/11/2021	27/11/2021
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/11/2021	27/11/2021
5387	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022		24/01/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	24/01/2022 24/01/2022		24/01/2022
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	24/01/2022 24/01/2022	24/01/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	24/01/2022 24/01/2022		24/01/2022
								F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	24/01/2022 24/01/2022	24/01/2022

		F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
				A0705	Battery Problem	24/01/2022	24/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
				A0705	Battery Problem	24/01/2022	24/01/2022
CT145	Cardiovascular devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
				A0705	Battery Problem	24/01/2022	24/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem	24/01/2022	24/01/2022
				A070504	Premature Discharge of Battery	24/01/2022	24/01/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022

								F1905	Device Revision or Replacement	A070504 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	24/01/2022 24/01/2022 24/01/2022	24/01/2022 24/01/2022 24/01/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	24/01/2022	24/01/2022	
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705 A070504	Premature Discharge of Battery Battery Problem Premature Discharge of Battery	24/01/2022 24/01/2022 24/01/2022	24/01/2022 24/01/2022 24/01/2022	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/01/2022	24/01/2022	
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022	
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Battery Problem	24/01/2022	24/01/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022	
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022	
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/01/2022	24/01/2022	
							F1905	Device Revision or Replacement	A070504 A0705	Premature Discharge of Battery Battery Problem	24/01/2022 24/01/2022	24/01/2022 24/01/2022	
5388	2022	All other reportable incidents			CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/01/2022	24/01/2022	
5389	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
5390	2022	All other reportable incidents			CT1258	Implantable defibrillators	F2301	Additional Device Required	A0705	Battery Problem			
5391	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0112	Dizziness	A090811	Unable to Obtain Readings			
							E0752	Unspecified Respiratory Problem	A090811	Unable to Obtain Readings			
							F08	Hospitalization or Prolonged Hospitalization	A090811	Unable to Obtain Readings			
					CT1150	Defibrillators	F19	Surgical Intervention	A0705	Battery Problem			
					CT1141	Electrodes/Leads and associated devices	F19	Surgical Intervention	A0705	Battery Problem			
					CT1146	Cardiovascular devices	F19	Surgical Intervention	A0705	Battery Problem			
					CT1233	Surgical	F19	Surgical Intervention	A0705	Battery Problem			
					CT12406	Implantable	F19	Surgical Intervention	A0705	Battery Problem			
					CT12407	Active implantable	F19	Surgical Intervention	A0705	Battery Problem			
					CT1258	Implantable defibrillators	F19	Surgical Intervention	A0705	Battery Problem			
					CT12727	Active implant devices/lancillaries	F19	Surgical Intervention	A0705	Battery Problem			
					CT12750	Implantable cardiac electrical stimulators and associated devices	F19	Surgical Intervention	A0705	Battery Problem			
					CT12866	Implantable cardiac electrical stimulators	F19	Surgical Intervention	A0705	Battery Problem			
					CT12985	Active	F19	Surgical Intervention	A0705	Battery Problem			
					CT13001	Implantable metal	F19	Surgical Intervention	A0705	Battery Problem			
					CT13002	Implantable synthetic polymer	F19	Surgical Intervention	A0705	Battery Problem			
					CT13006	Implantable inorganic material	F19	Surgical Intervention	A0705	Battery Problem			
					CT13007	Implantable ceramic	F19	Surgical Intervention	A0705	Battery Problem			
					CT1314	Electrically powered	F19	Surgical Intervention	A0705	Battery Problem			
					CT1321	Long-term surgical invasive	F19	Surgical Intervention	A0705	Battery Problem			
					CT1449	Generators and associated devices	F19	Surgical Intervention	A0705	Battery Problem			
					CT1981	Single use	F19	Surgical Intervention	A0705	Battery Problem			
					CT1983	Surgical invasive	F19	Surgical Intervention	A0705	Battery Problem			
5392	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071101	Difficult to Interrogate			
5393	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	F26	No Health Consequences or Impact	A071101	Difficult to Interrogate			
							E0601	Arrhythmia	A070101	Failure to Capture			
							F12	Serious Injury/ Illness/ Impairment	A071204	No Pacing			
5394	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
							F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
							F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
							F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
							F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
							F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem			
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
							F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem			
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			
							F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem			
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem			

						C1258	Implantable defibrillators	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C1263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C12726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C12727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C12750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C12866	implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C12985	Active	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C13001	Implantable metal	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C13002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C13006	Implantable inorganic material	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C13007	Implantable ceramic	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C1314	Electrically powered	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C1321	Long-term surgical invasive	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C1449	Generators and associated devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C1981	Single use	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						C1983	Surgical invasive	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
5395	2022	All other reportable incidents				C1258	Implantable defibrillators	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A01	Patient Device Interaction Problem		
								F2301	Additional Device Required	A01	Patient Device Interaction Problem		
5396	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator		C11010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C11147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C11150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1145	Cardiovascular devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1233	Surgical	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C12406	Implantable	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C12407	Active implantable	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1258	Implantable defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C12726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C12727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C12750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C12866	implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C12985	Active	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C13001	Implantable metal	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C13002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C13006	Implantable inorganic material	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C13007	Implantable ceramic	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1314	Electrically powered	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1449	Generators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1981	Single use	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						C1983	Surgical invasive	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
5397	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator		C11010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A0705	Battery Problem		
						C11147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem		
						C11150	Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem		
						C1141	Electrodes/Leads and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem		
						C1145	Cardiovascular devices	F1905	Device Revision or Replacement	A0705	Battery Problem		

					CT233	Surgical	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT2406	Implantable	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT2407	Active implantable	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT2727	Active implant devices/ancillaries	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT2985	Active	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT3001	Implantable metal	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT3006	Implantable inorganic material	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT3007	Implantable ceramic	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT314	Electrically powered	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT321	Long-term surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT440	Generators and associated devices	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT981	Single use	F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT983	Surgical invasive	F1905	Device Revision or Replacement	A0705	Battery Problem		
5398	2022	All other reportable incidents			CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem		
5399	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F1905	Device Revision or Replacement	A010402	Migration		
5400	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071205	Pacemaker Found in Back-Up Mode		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071205	Pacemaker Found in Back-Up Mode		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A071205	Pacemaker Found in Back-Up Mode		
									A0705	Battery Problem		
									A071205	Pacemaker Found in Back-Up Mode		
5401	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
5402	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		

						CT2407	Active implantable	E2403	No Health Consequences or Impact	A0705	Battery Problem			
								E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
						CT258	Implantable defibrillators	E2403	No Health Consequences or Impact	A0705	Battery Problem			
								F26	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
						CT2727	Active implant devices/ancillaries	E2403	No Health Consequences or Impact	A0705	Battery Problem			
								F26	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A0705	Battery Problem			
5403	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0138	Undesired Nerve Stimulation	A071205	Pacemaker Found in Back-Up Mode				
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071205	Pacemaker Found in Back-Up Mode			
5404	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F11	Non-Serious Injury/Illness/Impairment	A071205	Pacemaker Found in Back-Up Mode				
								E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem			
								F26	No Health Consequences or Impact	A0713	Defibrillation/Stimulation Problem			
5405	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator				
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator			
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator			
5406	2022	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices								
						CT1147	Defibrillators and associated devices							
						CT1150	Defibrillators							

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					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2985	Active	F26	No Health Consequences or Impact	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3001	implantable metal	F26	No Health Consequences or Impact	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A0705	Battery Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
5417	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
							F01	Change in Therapeutic Response	A040101	Fracture		
5418	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator		
5419	2022		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/10/2022	05/10/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	05/10/2022	05/10/2022
5420	2022	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A27	Appropriate Device Problem Term/Code not Available		
					CT1147	Defibrillators and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT1150	Defibrillators			A27	Appropriate Device Problem Term/Code not Available		
					CT141	Electrodes/Leads and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT145	Cardiovascular devices			A27	Appropriate Device Problem Term/Code not Available		
					CT233	Surgical			A27	Appropriate Device Problem Term/Code not Available		
					CT2406	Implantable			A27	Appropriate Device Problem Term/Code not Available		
					CT2407	Active implantable			A27	Appropriate Device Problem Term/Code not Available		
					CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
					CT263	Cardiographs and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT2726	Physiological monitoring/measuring devices			A27	Appropriate Device Problem Term/Code not Available		
					CT2727	Active implant devices/ancillaries			A27	Appropriate Device Problem Term/Code not Available		
					CT2750	Implantable cardiac electrical stimulators and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT2866	Implantable cardiac electrical stimulators			A27	Appropriate Device Problem Term/Code not Available		
					CT2985	Active			A27	Appropriate Device Problem Term/Code not Available		
					CT3001	Implantable metal			A27	Appropriate Device Problem Term/Code not Available		
					CT3002	Implantable synthetic polymer			A27	Appropriate Device Problem Term/Code not Available		
					CT3006	Implantable inorganic material			A27	Appropriate Device Problem Term/Code not Available		
					CT3007	Implantable ceramic			A27	Appropriate Device Problem Term/Code not Available		
					CT314	Electrically powered			A27	Appropriate Device Problem Term/Code not Available		
					CT321	Long-term surgical invasive			A27	Appropriate Device Problem Term/Code not Available		
					CT449	Generators and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT981	Single use			A27	Appropriate Device Problem Term/Code not Available		
					CT983	Surgical invasive			A27	Appropriate Device Problem Term/Code not Available		
5421	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Pacing Problem	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Pacing Problem	
5424	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/10/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/10/2022
									A070504	Premature Discharge of Battery	20/10/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/10/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/10/2022
									A070504	Premature Discharge of Battery	20/10/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/10/2022
									A0705	Battery Problem	20/10/2022

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								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2010/2022	2010/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	2010/2022	2010/2022
										A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
					CT3007	Implantable ceramic		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
					CT314	Electrically powered		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
					CT321	Long-term surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
					CT449	Generators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
					CT981	Single use		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
					CT983	Surgical invasive		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
								F1905	Device Revision or Replacement	A0705	Battery Problem	2010/2022	2010/2022
										A070504	Premature Discharge of Battery	2010/2022	2010/2022
6425	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
						CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2023	08/02/2023
				A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
CT141	Electrodes,Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2023	08/02/2023
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2023	08/02/2023
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2023	08/02/2023
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2023	08/02/2023
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2023	08/02/2023
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2023	08/02/2023
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	08/02/2023	08/02/2023
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/02/2023	08/02/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/02/2023	08/02/2023

				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2406	Implantable	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2407	Active implantable	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F2203	Imaging Required	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F2203	Imaging Required	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F2203	Imaging Required	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
				A070909	Overensing				
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
				A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
CT3001	Implantable metal	E2104	Electric Shock	A0709	Device Sensing Problem				

CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1150	Defibrillators	F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1151	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1145	Cardiovascular devices	F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT1233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2406	Implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Overensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Overensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

			F2203	Imaging Required	A070909 A071302 A090801	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
CT2407	Active implantable		E2104	Electric Shock	A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A090801	Signal Artifact/Noise			
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT2985	Active	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT3001	Implantable metal	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
F2203	Imaging Required	A070909	Overensing						
		A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise						
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				

						F2203	Imaging Required	A008001 A070909 A071302 A090801	Signal Artifact/Noise Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F2203	Imaging Required	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F2203	Imaging Required	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT1314	Electrically powered	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F2203	Imaging Required	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F2203	Imaging Required	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT449	Generators and associated devices	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F2203	Imaging Required	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT981	Single use	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F2203	Imaging Required	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
						F2203	Imaging Required	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
5432	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem			
5433	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem		
						F1903	Device Explanation	A07	Electrical /Electronic Property Problem			
5434	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023
						F1905	Device Revision or Replacement	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023
						F1905	Device Revision or Replacement	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023	13/01/2023 13/01/2023 13/01/2023

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5435	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023 13/01/2023	13/01/2023 13/01/2023
								A0705 A070504	Battery Problem Premature Discharge of Battery	13/01/2023 13/01/2023	13/01/2023 13/01/2023	
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem	13/01/2023 13/01/2023	13/01/2023 13/01/2023	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	13/01/2023 13/01/2023	13/01/2023 13/01/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023	13/01/2023	
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	13/01/2023 13/01/2023	13/01/2023 13/01/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023	13/01/2023	
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Battery Problem Premature Discharge of Battery	13/01/2023 13/01/2023	13/01/2023 13/01/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023	13/01/2023	
						F1905	Device Revision or Replacement	A0705 A070504	Battery Problem Premature Discharge of Battery	13/01/2023 13/01/2023	13/01/2023 13/01/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/01/2023	13/01/2023	
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	13/01/2023 13/01/2023	13/01/2023 13/01/2023
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery							

								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem				
								A070504	Premature Discharge of Battery				
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem				
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem				
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery				
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem				
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery				
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0705	Battery Problem				
								A070504	Premature Discharge of Battery				
5436	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
5437	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator			
								F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
5438	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
									A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
								F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
									A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
									A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
								F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
									A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
									A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
								F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
									A070504	Premature Discharge of Battery	05/07/2023	05/07/2023	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023	

CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
CT145	Cardiovascular devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
CT233	Surgical			A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
CT2407	Active implantable			A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
CT263	Cardiographs and associated devices			A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
CT2727	Active implant devices/ancillaries			A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
CT2866	Implantable cardiac electrical stimulators			A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
CT3001	Implantable metal			A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
CT3006	Implantable inorganic material			A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	05/07/2023	05/07/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/07/2023	05/07/2023

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							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/11/2022	29/11/2022
									A070504	Premature Discharge of Battery	29/11/2022	29/11/2022
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/11/2022	29/11/2022
5440	2022		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A070912	Incorrect Interpretation of Signal		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
5441	2022	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing	05/10/2022	05/10/2022
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	05/10/2022	05/10/2022
							F1903	Device Explanation	A070909	Oversensing	05/10/2022	05/10/2022
5442	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT1147	Defibrillators and associated devices	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT1150	Defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT141	Electrodes/Leads and associated devices	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT145	Cardiovascular devices	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT233	Surgical	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT2406	Implantable	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT2407	Active implantable	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT258	Implantable defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
					CT263	Cardiographs and associated devices	E020201	Anxiety	A070504	Premature Discharge of Battery	21/10/2022	21/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2022	21/10/2022

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5445	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
							A072201	High Impedance				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A0722	Impedance Problem				
							A072201	High Impedance				
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A0722	Impedance Problem				
							A072201	High Impedance				
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A0722	Impedance Problem				
							A072201	High Impedance				
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A0722	Impedance Problem				
							A072201	High Impedance				
					CT3001	implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT3002	implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A0722	Impedance Problem				
							A072201	High Impedance				
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT3007	implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A0722	Impedance Problem				
							A072201	High Impedance				
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A0722	Impedance Problem				
							A072201	High Impedance				
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A0722	Impedance Problem				
							A072201	High Impedance				
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
					F26	No Health Consequences or Impact	A072201	High Impedance				
							A0722	Impedance Problem				
5446	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		

				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT233	Surgical	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2406	Implantable	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2407	Active implantable	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs end associated devices	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

3447	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A071302 A090801 A1301	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal									
						CT983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal							
										F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal					
												CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	
					F10											Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise
						CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise							
										F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise					
					CT1150							Defibrillators	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
															F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise
						CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise							
										F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure						A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise
					CT1145							Cardiovascular devices	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
															F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise
						CT1233	Surgical	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise							
										F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure						A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise
					CT2406							Implantable	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
															F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise
						CT2407	Active implantable	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise							
										F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure						A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise
					CT258							Implantable defibrillators	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
															F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise
						CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise							

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT2985	Active	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT3001	Implantable metal	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT314	Electrically powered	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071302 A072201 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

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						CT449	Generators and associated devices	F1905 E2403 F08	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A24 A24 A24	No Apparent Device Problem No Apparent Device Problem No Apparent Device Problem	17/08/2020 17/08/2020 17/08/2020	17/08/2020 17/08/2020 17/08/2020
						CT981	Single use	F1905 E2403	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions	A24 A24	No Apparent Device Problem No Apparent Device Problem	17/08/2020 17/08/2020	17/08/2020 17/08/2020
						CT983	Surgical invasive	F1905 E2403 F08 F1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A24 A24 A24 A24	No Apparent Device Problem No Apparent Device Problem No Apparent Device Problem No Apparent Device Problem	17/08/2020 17/08/2020 17/08/2020 17/08/2020	17/08/2020 17/08/2020 17/08/2020 17/08/2020
5449	2022	All other reportable incidents				CT258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302 A072201 A090801	Overensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072201 A090801	Overensing Inappropriate/Inadequate Shock/Stimulation High Impedance Signal Artifact/Noise		
5450	2022	Unanticipated serious deterioration in state of health				CT258	Implantable defibrillators	F19	Surgical Intervention	A0722	Impedance Problem		
5451	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT1147	Defibrillators and associated devices	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT1150	Defibrillators	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT1150	Defibrillators	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT1141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT1141	Electrodes/Leads and associated devices	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT1145	Cardiovascular devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT1145	Cardiovascular devices	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT1233	Surgical	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT1233	Surgical	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT2406	Implantable	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT2406	Implantable	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT2407	Active implantable	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT2407	Active implantable	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT258	Implantable defibrillators	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT258	Implantable defibrillators	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT263	Cardiographs and associated devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT2726	Physiological monitoring/measuring devices	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT2726	Physiological monitoring/measuring devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT2727	Active implant devices/ancillaries	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT2866	Implantable cardiac electrical stimulators	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT2985	Active	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT2985	Active	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT3001	Implantable metal	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT3001	Implantable metal	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT3002	Implantable synthetic polymer	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT3006	Implantable inorganic material	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT3006	Implantable inorganic material	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT3007	Implantable ceramic	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT3007	Implantable ceramic	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT314	Electrically powered	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT314	Electrically powered	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT321	Long-term surgical invasive	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT321	Long-term surgical invasive	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT449	Generators and associated devices	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT449	Generators and associated devices	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT981	Single use	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT981	Single use	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
						CT983	Surgical invasive	F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
						CT983	Surgical invasive	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
5452	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1147	Defibrillators and associated devices	E0112 E0601 F26	Dizziness Arrhythmia No Health Consequences or Impact	A070909 A19 A070909 A19 A070909	Overensing Environmental Compatibility Problem Overensing Environmental Compatibility Problem Overensing		
						CT1150	Defibrillators	E0112 E0601 F26	Dizziness Arrhythmia No Health Consequences or Impact	A070909 A19 A070909 A19 A070909	Overensing Environmental Compatibility Problem Overensing Environmental Compatibility Problem Overensing		
						CT141	Electrodes/Leads and associated devices	E0112 E0601 F26	Dizziness Arrhythmia No Health Consequences or Impact	A070909 A19 A070909 A19 A070909	Overensing Environmental Compatibility Problem Overensing Environmental Compatibility Problem Overensing		
						CT145	Cardiovascular devices	E0112 E0601	Dizziness Arrhythmia	A070909 A19 A070909	Overensing Environmental Compatibility Problem Overensing		

		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT233	Surgical	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT2406	Implantable	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT2407	Active implantable	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT258	Implantable defibrillators	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT2727	Active implant devices/ancillaries	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT2866	Implantable cardiac electrical stimulators	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT2985	Active	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT3001	Implantable metal	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT3002	Implantable synthetic polymer	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT3006	Implantable inorganic material	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT3007	Implantable ceramic	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT314	Electrically powered	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT321	Long-term surgical invasive	E0112	Dizziness	A070909	Oversensing		
		E0601	Arrhythmia	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
		F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		
CT449	Generators and associated devices	E0112	Dizziness	A19	Environmental Compatibility Problem		
				A070909	Oversensing		
				A19	Environmental Compatibility Problem		

							E0601	Arrhythmia	A070909	Oversensing		
							F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
									A070909	Oversensing		
									A19	Environmental Compatibility Problem		
						CT981		Single use	A070909	Oversensing		
							E0112	Dizziness	A19	Environmental Compatibility Problem		
							E0601	Arrhythmia	A070909	Oversensing		
							F26	No Health Consequences or Impact	A19	Environmental Compatibility Problem		
									A070909	Oversensing		
									A19	Environmental Compatibility Problem		
						CT983		Surgical invasive	A19	Environmental Compatibility Problem		
							E0112	Dizziness	A070909	Oversensing		
							E0601	Arrhythmia	A19	Environmental Compatibility Problem		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A19	Environmental Compatibility Problem		
5453	2022	All other reportable incidents				CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
5454	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1147		Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT1150		Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT141		Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT145		Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT233		Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2406		Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2407		Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2727		Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2750		Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2866		Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2985		Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT3001		Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT3002		Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT3006		Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT3007		Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT314		Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT321		Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT449		Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT981		Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT983		Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5455	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010		Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F1905	Device Revision or Replacement	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						CT1147		Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		A070909	Overensing					
		A071302	Inappropriate/Inadequate Shock/Stimulation					
		A090801	Signal Artifact/Noise					
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		A070909	Overensing					
		A071302	Inappropriate/Inadequate Shock/Stimulation					
		A090801	Signal Artifact/Noise					
CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		A070909	Overensing					
		A071302	Inappropriate/Inadequate Shock/Stimulation					
		A090801	Signal Artifact/Noise					
CT233	Surgical	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		A070909	Overensing					
		A071302	Inappropriate/Inadequate Shock/Stimulation					
		A090801	Signal Artifact/Noise					
CT2406	Implantable	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		A070909	Overensing					
		A071302	Inappropriate/Inadequate Shock/Stimulation					
		A090801	Signal Artifact/Noise					
CT2407	Active implantable	E2104	Electric Shock	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F1905	Device Revision or Replacement	A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		A070909	Overensing					
		A071302	Inappropriate/Inadequate Shock/Stimulation					

CT258	Implantable defibrillators	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Overensing		

						F2203	Imaging Required	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F1905	Device Revision or Replacement	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F2203	Imaging Required	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F1905	Device Revision or Replacement	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F2203	Imaging Required	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F1905	Device Revision or Replacement	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F2203	Imaging Required	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F1905	Device Revision or Replacement	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
						F2203	Imaging Required	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090801	Signal Artifact/Noise		
5456	2022	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A26	Insufficient Device Problem Information	
					CT1147	Defibrillators and associated devices			A26	Insufficient Device Problem Information	
					CT1150	Defibrillators			A26	Insufficient Device Problem Information	
					CT141	Electrodes/Leads and associated devices			A26	Insufficient Device Problem Information	
					CT145	Cardiovascular devices			A26	Insufficient Device Problem Information	
					CT233	Surgical			A26	Insufficient Device Problem Information	
					CT2406	Implantable			A26	Insufficient Device Problem Information	
					CT2407	Active implantable			A26	Insufficient Device Problem Information	
					CT258	Implantable defibrillators			A26	Insufficient Device Problem Information	
					CT263	Cardiographs and associated devices			A26	Insufficient Device Problem Information	
					CT2726	Physiological monitoring/measuring devices			A26	Insufficient Device Problem Information	
					CT2727	Active implant devices/ancillaries			A26	Insufficient Device Problem Information	
					CT2750	Implantable cardiac electrical stimulators and associated devices			A26	Insufficient Device Problem Information	
					CT2866	Implantable cardiac electrical stimulators			A26	Insufficient Device Problem Information	
					CT2985	Active			A26	Insufficient Device Problem Information	
					CT3001	Implantable metal			A26	Insufficient Device Problem Information	
					CT3002	Implantable synthetic polymer			A26	Insufficient Device Problem Information	
					CT3006	Implantable inorganic material			A26	Insufficient Device Problem Information	
					CT3007	Implantable ceramic			A26	Insufficient Device Problem Information	
					CT314	Electrically powered			A26	Insufficient Device Problem Information	
					CT321	Long-term surgical invasive			A26	Insufficient Device Problem Information	
					CT449	Generators and associated devices			A26	Insufficient Device Problem Information	
					CT981	Single use			A26	Insufficient Device Problem Information	
					CT983	Surgical invasive			A26	Insufficient Device Problem Information	

9457	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem						
9458	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022				
							F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022				
							F1903	Device Explanation	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022				
							F2203	Imaging Required	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022				
							F23	Unexpected Medical Intervention	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022				
							CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022		
									F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022		
						F1903			Device Explanation	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022			
						F2203			Imaging Required	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022			
						F23			Unexpected Medical Intervention	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022			
						CT1150			Defibrillators	E2104	Electric Shock	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
										F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
										F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
								F1903		Device Explanation	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022		
								F2203		Imaging Required	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022		
								F23		Unexpected Medical Intervention	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022		
								CT1141		Electrodes/Leads and associated devices	E2104	Electric Shock	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022
											F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022
											F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022
						F1903			Device Explanation		A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022		

					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203		Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23		Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT145	Cardiovascular devices	E2104		Electric Shock	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903		Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203		Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23		Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT1233	Surgical	E2104		Electric Shock	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903		Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203		Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Oversensing	01/12/2022	01/12/2022</

				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903	Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903	Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903	Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903	Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Overensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022

CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
		F1903	Device Explanation	A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention	A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
		F1903	Device Explanation	A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention	A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
		F1903	Device Explanation	A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention	A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
		F1903	Device Explanation	A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022

					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT3001	Implantable metal	E2104	Electric Shock		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903	Device Explanation		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT3002	Implantable synthetic polymer	E2104	Electric Shock		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903	Device Explanation		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT3006	Implantable inorganic material	E2104	Electric Shock		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F1903	Device Explanation		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F2203	Imaging Required		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
CT3007	Implantable ceramic	E2104	Electric Shock		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem	01/12/2022	01/12/2022
					A070909	Overensing	01/12/2022	01/12/2022

CT314	Electrically powered	F1903	Device Explanation	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022
CT981	Single use	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A0709	Device Sensing Problem	01/12/2022	01/12/2022
				A070909	Oversensing	01/12/2022	01/12/2022

						F08	Hospitalization or Prolonged Hospitalization	A09801 A0709 A070909 A071302 A09801	Signal Artifact/Noise Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F1903	Device Explanation	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F2203	Imaging Required	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F23	Unexpected Medical Intervention	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
				CT983	Surgical Invasive	E2104	Electric Shock	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F1903	Device Explanation	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F2203	Imaging Required	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
						F23	Unexpected Medical Intervention	A0709 A070909 A071302 A09801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022	
5459	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT233	Surgical	E2104	Electric Shock	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT2406	Implantable	E2104	Electric Shock	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A09801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT2407	Active implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801 A070909 A071302 A090801	Signal Artifact/Noise Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT258	implantable defibrillators	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT2750	implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT2806	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT2985	Active	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT3001	Implantable metal	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT3002	implantable synthetic polymer	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT3007	implantable ceramic	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT314	Electrically powered	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT449	Generators and associated devices	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
CT981	Single use	E2104	Electric Shock	A070909	Oversensing		

					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions		A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
					A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
					A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
					A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	24/11/2022	24/11/2022
					A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
					A070909	Oversensing	24/11/2022	24/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022

					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F1905	Device Revision or Replacement		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022
					A071302	Inappropriate/Inadequate Shock/Stimulation	2/11/2022	2/11/2022
					A090801	Signal Artifact/Noise	2/11/2022	2/11/2022
					A1301	Failure to Read Input Signal	2/11/2022	2/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	2/11/2022	2/11/2022
					A070504	Premature Discharge of Battery	2/11/2022	2/11/2022
					A070909	Oversensing	2/11/2022	2/11/2022

				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F1905	Device Revision or Replacement	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
				A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
				A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/11/2022	24/11/2022
				A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
				A070909	Oversensing	24/11/2022	24/11/2022
				A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022

									A070909	Oversensing	24/11/2022	24/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
									A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
									A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	24/11/2022	24/11/2022
									A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
									A070909	Oversensing	24/11/2022	24/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
									A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
									A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2022	24/11/2022
									A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
									A070909	Oversensing	24/11/2022	24/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
									A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
									A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	24/11/2022	24/11/2022
									A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
									A070909	Oversensing	24/11/2022	24/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
									A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
									A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	24/11/2022	24/11/2022
									A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
									A070909	Oversensing	24/11/2022	24/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
									A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
									A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/11/2022	24/11/2022
									A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
									A070909	Oversensing	24/11/2022	24/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
									A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
									A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	24/11/2022	24/11/2022
									A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
									A070909	Oversensing	24/11/2022	24/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
									A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
									A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
						F1905	Device Revision or Replacement		A0705	Battery Problem	24/11/2022	24/11/2022
									A070504	Premature Discharge of Battery	24/11/2022	24/11/2022
									A070909	Oversensing	24/11/2022	24/11/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/11/2022	24/11/2022
									A090801	Signal Artifact/Noise	24/11/2022	24/11/2022
									A1301	Failure to Read Input Signal	24/11/2022	24/11/2022
5462	2022	All other reportable incidents	97265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		
									A072202	Low Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact		A072201	High Impedance		

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				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		

				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071201	Failure to Convert Rhythm		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		

					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071201 A071302 A090801 A1301	Oversensing Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071201 A071302 A090801 A1301	Oversensing Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909 A071201 A071302 A090801 A1301	Oversensing Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071201 A071302 A090801 A1301	Oversensing Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT981	Single use	E2104	Electric Shock	A070909 A071201 A071302 A090801 A1301	Oversensing Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071201 A071302 A090801 A1301	Oversensing Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT983	Surgical invasive	E2104	Electric Shock	A070909 A071201 A071302 A090801 A1301	Oversensing Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071201 A071302 A090801 A1301	Oversensing Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
5465	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT233	Surgical	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2406	Implantable	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2407	Active implantable	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		

				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		

					A0908 A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT233	Surgical				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT2406	Implantable				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT2407	Active implantable				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT258	Implantable defibrillators				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT263	Cardiographs and associated devices				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT2726	Physiological monitoring/measuring devices				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT2727	Active implant devices/ancillaries				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT2750	Implantable cardiac electrical stimulators and associated devices				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT2868	Implantable cardiac electrical stimulators				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT2985	Active				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT3001	Implantable metal				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT3002	Implantable synthetic polymer				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT3008	Implantable inorganic material				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
CT3007	Implantable ceramic				A0908	High Impedance	04/11/2022	04/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
		F08	Hospitalization or Prolonged Hospitalization		A0908	High Impedance	04/11/2022	04/11/2022
		F1905	Device Revision or Replacement		A072201	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
					A0908	High Impedance	04/11/2022	04/11/2022

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	04/11/2022	04/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	04/11/2022	04/11/2022
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	04/11/2022	04/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	04/11/2022	04/11/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	04/11/2022	04/11/2022
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	04/11/2022	04/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	04/11/2022	04/11/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	04/11/2022	04/11/2022
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	04/11/2022	04/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	04/11/2022	04/11/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	04/11/2022	04/11/2022
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	04/11/2022	04/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	04/11/2022	04/11/2022
							F1905	Device Revision or Replacement	A072201	High Impedance	04/11/2022	04/11/2022
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/11/2022	04/11/2022
5469	2022	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A27	Appropriate Device Problem Term/Code not Available		
					CT1147	Defibrillators and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT1150	Defibrillators			A27	Appropriate Device Problem Term/Code not Available		
					CT141	Electrodes/Leads and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT145	Cardiovascular devices			A27	Appropriate Device Problem Term/Code not Available		
					CT233	Surgical			A27	Appropriate Device Problem Term/Code not Available		
					CT2406	Implantable			A27	Appropriate Device Problem Term/Code not Available		
					CT2407	Active implantable			A27	Appropriate Device Problem Term/Code not Available		
					CT258	Implantable defibrillators			A27	Appropriate Device Problem Term/Code not Available		
					CT263	Cardiographic and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT2726	Physiological monitoring/measuring devices			A27	Appropriate Device Problem Term/Code not Available		
					CT2727	Active implant devices/ancillaries			A27	Appropriate Device Problem Term/Code not Available		
					CT2750	Implantable cardiac electrical stimulators and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT2866	Implantable cardiac electrical stimulators			A27	Appropriate Device Problem Term/Code not Available		
					CT2985	Active			A27	Appropriate Device Problem Term/Code not Available		
					CT3001	Implantable metal			A27	Appropriate Device Problem Term/Code not Available		
					CT3002	Implantable synthetic polymer			A27	Appropriate Device Problem Term/Code not Available		
					CT3006	Implantable inorganic material			A27	Appropriate Device Problem Term/Code not Available		
					CT3007	Implantable ceramic			A27	Appropriate Device Problem Term/Code not Available		
					CT314	Electrically powered			A27	Appropriate Device Problem Term/Code not Available		
					CT321	Long-term surgical invasive			A27	Appropriate Device Problem Term/Code not Available		
					CT449	Generators and associated devices			A27	Appropriate Device Problem Term/Code not Available		
					CT981	Single use			A27	Appropriate Device Problem Term/Code not Available		
					CT983	Surgical invasive			A27	Appropriate Device Problem Term/Code not Available		
5470	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	29/09/2022	29/09/2022
							P24	Insufficient Health Impact Information	A0203	Defective Device	29/09/2022	29/09/2022
5471	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F02	Death	A0712	Pacing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F2306	Resuscitation	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT1150	Defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F02	Death	A0712	Pacing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F2306	Resuscitation	A0712	Pacing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		

CT145	Cardiovascular devices	F02	Death	A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
				A0709	Device Sensing Problem			
		F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
				A0709	Device Sensing Problem			
		F1203	Life Threatening Illness or Injury	A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
				A0709	Device Sensing Problem			
		F2306	Resuscitation	A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
				A0709	Device Sensing Problem			
CT145	Cardiovascular devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F02	Death	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
F2306	Resuscitation	A0709	Device Sensing Problem					
		A0712	Pacing Problem					
		A071301	Failure to Deliver Shock/Stimulation					
CT233	Surgical	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F02	Death	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
F2306	Resuscitation	A0709	Device Sensing Problem					
		A0712	Pacing Problem					
		A071301	Failure to Deliver Shock/Stimulation					
CT2406	Implantable	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F02	Death	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
F2306	Resuscitation	A0709	Device Sensing Problem					
		A0712	Pacing Problem					
		A071301	Failure to Deliver Shock/Stimulation					
CT2407	Active implantable	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F02	Death	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
F2306	Resuscitation	A0709	Device Sensing Problem					
		A0712	Pacing Problem					
		A071301	Failure to Deliver Shock/Stimulation					
CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F02	Death	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
				A0712	Pacing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
F2306	Resuscitation	A0709	Device Sensing Problem					
		A0712	Pacing Problem					
		A071301	Failure to Deliver Shock/Stimulation					

CT2727	Active implant devices/ancillaries	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2985	Active	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3001	Implantable metal	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3002	Implantable synthetic polymer	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F02	Death	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A0712	Pacing Problem		
				A071301	Failure to Deliver Shock/Stimulation		

CT3006	Implantable inorganic material	E060110	Ventricular Fibrillation	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F02	Death	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
CT3007	Implantable ceramic	E060110	Ventricular Fibrillation	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F02	Death	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
CT314	Electrically powered	E060110	Ventricular Fibrillation	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F02	Death	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
CT321	Long-term surgical invasive	E060110	Ventricular Fibrillation	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F02	Death	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
CT449	Generators and associated devices	E060110	Ventricular Fibrillation	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F02	Death	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
CT981	Single use	E060110	Ventricular Fibrillation	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F02	Death	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A0712	Pacing Problem		
		F2306	Resuscitation	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070908	Failure to Sense	28/09/2022	28/09/2022
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070908	Failure to Sense	28/09/2022	28/09/2022
							F1908	Prolonged Surgery	A070908	Failure to Sense	28/09/2022	28/09/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070908	Failure to Sense	28/09/2022	28/09/2022
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070908	Failure to Sense	28/09/2022	28/09/2022
							F1908	Prolonged Surgery	A070908	Failure to Sense	28/09/2022	28/09/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070908	Failure to Sense	28/09/2022	28/09/2022
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070908	Failure to Sense	28/09/2022	28/09/2022
							F1908	Prolonged Surgery	A070908	Failure to Sense	28/09/2022	28/09/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070908	Failure to Sense	28/09/2022	28/09/2022
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070908	Failure to Sense	28/09/2022	28/09/2022
							F1908	Prolonged Surgery	A070908	Failure to Sense	28/09/2022	28/09/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070908	Failure to Sense	28/09/2022	28/09/2022
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070908	Failure to Sense	28/09/2022	28/09/2022
							F1908	Prolonged Surgery	A070908	Failure to Sense	28/09/2022	28/09/2022
8473	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071205	Pacemaker Found in Back-Up Mode		
8474	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	29/12/2022	29/12/2022
									A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/12/2022	29/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/12/2022	29/12/2022
									A0705	Battery Problem	29/12/2022	29/12/2022

						F26	No Health Consequences or Impact	A0705	Battery Problem			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
5478	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

					CT2406	Implantable	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT2407	Active implantable	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT2985	Active	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT3001	Implantable metal	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT3006	implantable inorganic material	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT314	Electrically powered	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT981	Single use	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
5479	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/11/2022	15/11/2022	
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022	
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/11/2022	15/11/2022	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022	

		F1905	Device Revision or Replacement	A0705	Battery Problem	15/11/2022	15/11/2022
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT2726	Physiological monitoring/measuring devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT2727	Active implant devices/ancillaries	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT2985	Active	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT3002	Implantable synthetic polymer	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT3006	Implantable inorganic material	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT314	Electrically powered	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT321	Long-term surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
CT983	Surgical invasive	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
				A0705	Battery Problem	15/11/2022	15/11/2022
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
									A0705	Battery Problem	15/11/2022	15/11/2022
									A070504	Premature Discharge of Battery	15/11/2022	15/11/2022
5480	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	22/11/2022	
							F01	Change in Therapeutic Response	A160503	Inappropriate or Unexpected Reset	22/11/2022	
5481	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT1276	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
CT1277	Active implant devices/ancillaries	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F23	Unexpected Medical Intervention	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
CT2985	Active	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

CT3001	Implantable metal	F2203	Imaging Required	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2104	Electric Shock	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
F2203	Imaging Required	A098001	Signal Artifact/Noise					
		A070909	Overensing					
		A071302	Inappropriate/Inadequate Shock/Stimulation					
F23	Unexpected Medical Intervention	A098001	Signal Artifact/Noise					
		A070909	Overensing					
		A071302	Inappropriate/Inadequate Shock/Stimulation					
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3006	Implantable inorganic material	E2104	Electric Shock	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3007	Implantable ceramic	E2104	Electric Shock	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT314	Electrically powered	E2104	Electric Shock	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT321	Long-term surgical invasive	E2104	Electric Shock	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT449	Generators and associated devices	E2104	Electric Shock	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F23	Unexpected Medical Intervention	A098001	Signal Artifact/Noise			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			

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									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2203	Imaging Required	A090801	Signal Artifact/Noise			
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
					CT149	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2203	Imaging Required	A090801	Signal Artifact/Noise			
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2203	Imaging Required	A090801	Signal Artifact/Noise			
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2203	Imaging Required	A090801	Signal Artifact/Noise			
								A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
						F23	Unexpected Medical Intervention	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
5483	2022		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/11/2022	17/11/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/11/2022	17/11/2022
5484	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening illness or injury	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
								A071301	Failure to Deliver Shock/Stimulation			
					CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening illness or injury	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
								A071301	Failure to Deliver Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening illness or injury	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
					CT145	Cardiovascular devices	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening illness or injury	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
								A071301	Failure to Deliver Shock/Stimulation			
					CT233	Surgical	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
								A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening illness or injury	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
					CT2406	Implantable	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening illness or injury	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
								A071301	Failure to Deliver Shock/Stimulation			
					CT2407	Active implantable	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
								A071301	Failure to Deliver Shock/Stimulation			

						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
					CT258	Implantable defibrillators	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
					CT2985	Active	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT3001	Implantable metal	E060109	Tachycardia	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT3006	Implantable inorganic material	E060109	Tachycardia	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT314	Electrically powered	E060109	Tachycardia	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT449	Generators and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
					CT981	Single use	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								A0709	Device Sensing Problem			
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
					CT983	Surgical invasive	E060109	Tachycardia	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
5485	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		

					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
5486	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		

5486	2022	All other reportable incidents	35652	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	P26	No Health Consequences or Impact	A1803	Failure of Device to Self-Test			
							E2104	Electric Shock	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing			

CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		

			Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F23	Unexpected Medical Intervention	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
CT2985	Active	E2104	Electric Shock	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F23	Unexpected Medical Intervention	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
CT3001	Implantable metal	E2104	Electric Shock	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F23	Unexpected Medical Intervention	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F23	Unexpected Medical Intervention	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
CT3006	Implantable inorganic material	E2104	Electric Shock	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
		F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			

CT3007	Implantable ceramic	F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
CT314	Electrically powered	F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
CT321	Long-term surgical invasive	F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
CT449	Generators and associated devices	F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A0709 A071302 A090801 A1301	Failure to Read Input Signal Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
						F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
						F23	Unexpected Medical Intervention	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
				CT983	Surgical invasive	E2104	Electric Shock	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
						F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
						F23	Unexpected Medical Intervention	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
5489	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301 A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304 A0705 A070504 A1304	Battery Problem Premature Discharge of Battery Telemetry Discrepancy	
						F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		

CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A1304	Telemetry Discrepancy		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
				A0705	Battery Problem		

									A070504	Premature Discharge of Battery		
									A1304	Telemetry Discrepancy		
5490	2022	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices						
					CT1147	Defibrillators and associated devices						
					CT1150	Defibrillators						
					CT141	Electrodes/Leads and associated devices						
					CT145	Cardiovascular devices						
					CT233	Surgical						
					CT2406	Implantable						
					CT2407	Active implantable						
					CT258	Implantable defibrillators						
					CT263	Cardiographs and associated devices						
					CT2726	Physiological monitoring/measuring devices						
					CT2727	Active implant devices/ancillaries						
					CT2750	Implantable cardiac electrical stimulators and associated devices						
					CT2866	Implantable cardiac electrical stimulators						
					CT2985	Active						
					CT3001	Implantable metal						
					CT3002	Implantable synthetic polymer						
					CT3006	Implantable inorganic material						
					CT3007	Implantable ceramic						
					CT314	Electrically powered						
					CT321	Long-term surgical invasive						
					CT449	Generators and associated devices						
					CT981	Single use						
					CT983	Surgical invasive						
5491	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
5493	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
5494	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
5495	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
5496	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5497	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5498	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2311	Discomfort	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT1150	Defibrillators	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2311	Discomfort	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT145	Cardiovascular devices	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2311	Discomfort	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
					CT2406	Implantable	E2311	Discomfort	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5508	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							P08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1903	Device Explantation	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/07/2020	27/07/2020
5509	2019	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
5510	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		

CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT2406	Implantable	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F13	Misdiagnosis/ Misclassification	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A070909	Oversensing		
		F13	Misdiagnosis/ Misclassification	A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

							F13	Mediagnosis/ Misclassification	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F13	Mediagnosis/ Misclassification	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F13	Mediagnosis/ Misclassification	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F13	Mediagnosis/ Misclassification	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F13	Mediagnosis/ Misclassification	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F13	Mediagnosis/ Misclassification	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F13	Mediagnosis/ Misclassification	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F13	Mediagnosis/ Misclassification	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
5511	2020	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT1147	Defibrillators and associated devices	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT1150	Defibrillators	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT145	Cardiovascular devices	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT233	Surgical	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2406	Implantable	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2407	Active implantable	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT258	Implantable defibrillators	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2726	Physiological monitoring/measuring devices	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		
							F02	Death	A070910	Undersensing		
					CT2985	Active	E060109	Tachycardia	A070910	Undersensing		
							E2401	Insufficient Information	A070910	Undersensing		

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					CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT145	Cardiovascular devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2406	Implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3002	Implantable synthetic polymer	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT3007	Implantable ceramic	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT321	Long-term surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT981	Single use	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
5515	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
5516	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
5517	2022	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
5518	2022	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2311	Discomfort	A070504	Premature Discharge of Battery			
									A070909	Oversensing			
							F12	Serious Injury/Illness/ Impairment	A070912	Incorrect Interpretation of Signal			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
									A070912	Incorrect Interpretation of Signal			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
5519	2022	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A090801	Signal Artifact/Noise			
									A1107	Data Problem			

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A0908 A090801 A1107	Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise Data Problem		
5520	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F11	Non-Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F11	Non-Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F11	Non-Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery		
5521	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
5522	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
5523	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
5524	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023 03/02/2023	03/02/2023 03/02/2023

5525	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023																												
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023																												
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023																														
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023																												
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023																														
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing																														
							A070910	Undersensing																																
							A0712	Pacing Problem																																
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing																														
							A070910	Undersensing																																
A0712	Pacing Problem																																							
5526	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing																														
							A070910	Undersensing																																
							A0712	Pacing Problem																																
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing																														
							A070910	Undersensing																																
							A0712	Pacing Problem																																
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing																														
							A070910	Undersensing																																
							A0712	Pacing Problem																																
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing																														
A070910	Undersensing																																							
A0712	Pacing Problem																																							
5527	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery																														
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery																														
							5528	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery																							
														F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery																							
														5529	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery																
																					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery																
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
																												F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																												5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																													E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
							5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators																						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
														5530	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
																																			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504	Premature Discharge of Battery		
																					5530	2023	All other reportable incidents	35852	Single-chamber implantable defibr															

5531	2023	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT1150	Defibrillators	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT1141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT1145	Cardiovascular devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT233	Surgical	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT2406	Implantable	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT2407	Active implantable	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT2985	Active	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
				CT3001	Implantable metal	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
								A070504	Premature Discharge of Battery		
CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem						
				A070504	Premature Discharge of Battery						
CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem						
				A070504	Premature Discharge of Battery						
CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem						
				A070504	Premature Discharge of Battery						
CT314	Electrically powered	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem						
				A070504	Premature Discharge of Battery						
CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem						
				A070504	Premature Discharge of Battery						
CT449	Generators and associated devices	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem						
				A070504	Premature Discharge of Battery						
CT981	Single use	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem						
				A070504	Premature Discharge of Battery						
CT983	Surgical invasive	F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem						
				A070504	Premature Discharge of Battery						
5532	2023	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
								A0705	Battery Problem		
				CT1147	Defibrillators and associated devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT1150	Defibrillators	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT1141	Electrodes/Leads and associated devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT1145	Cardiovascular devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT233	Surgical	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT2406	Implantable	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT2407	Active implantable	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT2726	Physiological monitoring/measuring devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT2985	Active	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
				CT3001	Implantable metal	F26	No Health Consequences or Impact	A0705	Battery Problem		
								A0705	Battery Problem		
CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A0705	Battery Problem						
				A0705	Battery Problem						
CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A0705	Battery Problem						
				A0705	Battery Problem						
CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A0705	Battery Problem						
				A0705	Battery Problem						
CT314	Electrically powered	F26	No Health Consequences or Impact	A0705	Battery Problem						
				A0705	Battery Problem						
CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A0705	Battery Problem						
				A0705	Battery Problem						
CT449	Generators and associated devices	F26	No Health Consequences or Impact	A0705	Battery Problem						
				A0705	Battery Problem						
CT981	Single use	F26	No Health Consequences or Impact	A0705	Battery Problem						
				A0705	Battery Problem						
CT983	Surgical invasive	F26	No Health Consequences or Impact	A0705	Battery Problem						
				A0705	Battery Problem						
5533	2023	All other reportable incidents	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0368	Noise, Audible		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0508	Noise, Audible		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0508	Noise, Audible		
								A070909	Oversensing		
						F15	Recognized Device or Procedural Complication	A0508	Noise, Audible		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
				CT1150	Defibrillators	E2104	Electric Shock	A0508	Noise, Audible		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0368	Noise, Audible		
				A070909	Oversensing						
				A071302	Inappropriate/Inadequate Shock/Stimulation						
				A0368	Noise, Audible						
				A070909	Oversensing						

[illegible]

[illegible]

CT2406	Implantable	F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
F1901	Additional Surgery			A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
CT2727	Active implant devices/ancillaries			E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
F1901	Additional Surgery			A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
CT2866	Implantable cardiac electrical stimulators			E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
F1901	Additional Surgery			A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
CT3001	Implantable metal			E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
F1901	Additional Surgery			A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
CT3006	Implantable inorganic material			E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
F1901	Additional Surgery			A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
CT314	Electrically powered			E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
F1901	Additional Surgery			A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
CT449	Generators and associated devices			E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022
						A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022		
				A070908	Failure to Sense	08/11/2022	08/11/2022		
				A072201	High Impedance	08/11/2022	08/11/2022		
		CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
						A070908	Failure to Sense	08/11/2022	08/11/2022

								F1901	Additional Surgery	A072201	High Impedance	08/11/2022	08/11/2022
										A070101	Failure to Capture	08/11/2022	08/11/2022
										A070908	Failure to Sense	08/11/2022	08/11/2022
										A072201	High Impedance	08/11/2022	08/11/2022
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A070101	Failure to Capture	08/11/2022	08/11/2022
										A070908	Failure to Sense	08/11/2022	08/11/2022
										A072201	High Impedance	08/11/2022	08/11/2022
							F1901	Additional Surgery		A070101	Failure to Capture	08/11/2022	08/11/2022
										A070908	Failure to Sense	08/11/2022	08/11/2022
										A072201	High Impedance	08/11/2022	08/11/2022
5545	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	21/02/2023	21/02/2023
5546	2023				CT258	Implantable defibrillators				A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
5547	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2312	Fatigue		A180503	Inappropriate or Unexpected Reset	10/02/2023	10/02/2023
							F1901	Additional Surgery		A180503	Inappropriate or Unexpected Reset	10/02/2023	10/02/2023
5548	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
							F26	No Health Consequences or Impact		A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
							F26	No Health Consequences or Impact		A090801	Signal Artifact/Noise		
										A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
							F26	No Health Consequences or Impact		A090801	Signal Artifact/Noise		
										A070909	Oversensing		
5549	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock		A090801	Signal Artifact/Noise		
										A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
5550	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
							F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
							F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
							F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
							F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
							F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		
							F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
										A0722	Impedance Problem		
										A090804	False Positive Result		
										A090805	Incorrect Measurement		

CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
		F26	No Health Consequences or Impact	A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F26	No Health Consequences or Impact	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A090804	False Positive Result		
				A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
		F26	No Health Consequences or Impact	A0722	Impedance Problem		
				A090804	False Positive Result		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
		F26	No Health Consequences or Impact	A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F26	No Health Consequences or Impact	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A090804	False Positive Result		
				A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
		F26	No Health Consequences or Impact	A0722	Impedance Problem		
				A090804	False Positive Result		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
		F26	No Health Consequences or Impact	A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F26	No Health Consequences or Impact	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A090804	False Positive Result		
				A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
		F26	No Health Consequences or Impact	A0722	Impedance Problem		
				A090804	False Positive Result		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A090804	False Positive Result		
				A090805	Incorrect Measurement		

									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
						F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
						F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
						F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
						F26	No Health Consequences or Impact		A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
5551	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		

						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
								A0908	Incorrect, Inadequate or Imprecise Result or Readings			
5552	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/02/2023	20/02/2023
5553	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5554	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023
							F26	No Health Consequences or Impact	A072201	High Impedance	16/01/2023	16/01/2023
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	16/01/2023	16/01/2023

		F1001	Absence of Treatment	A0709	Device Sensing Problem		
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2407	Active implantable	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2985	Active	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3001	Implantable metal	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3002	Implantable synthetic polymer	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
CT3006	Implantable inorganic material	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3007	Implantable ceramic	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT314	Electrically powered	E060109	Tachycardia	A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1001	Absence of Treatment	A0709	Device Sensing Problem		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

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						F08	Hospitalization or Prolonged Hospitalization	A160601	Premature Elective Replacement Indicator	12/09/2022	12/09/2022
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/09/2022	12/09/2022
								A160601	Premature Elective Replacement Indicator	12/09/2022	12/09/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/09/2022
								A160601	Premature Elective Replacement Indicator	12/09/2022	12/09/2022
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/09/2022	12/09/2022
								A160601	Premature Elective Replacement Indicator	12/09/2022	12/09/2022
						F1903	Device Explanation	A070504	Premature Discharge of Battery	12/09/2022	12/09/2022
								A160601	Premature Elective Replacement Indicator	12/09/2022	12/09/2022
5563	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		

							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5564	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A070903	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
5565	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5566	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5567	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
5568	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/05/2023	04/05/2023

								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem	
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F2203	Imaging Required	A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A1301	Failure to Read Input Signal	
								A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F2203	Imaging Required	A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem	
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F2203	Imaging Required	A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem	
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
						F2203	Imaging Required	A0709	Device Sensing Problem		
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A1301	Failure to Read Input Signal		
5572	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A070909	Oversensing	
5573	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A072201	High Impedance		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A072201	High Impedance		
								A090801	Signal Artifact/Noise		
5574	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	09/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	09/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	09/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2022
					CT141	Electrodes/Leads end associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	09/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	09/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	09/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2022
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	09/11/2022
							F1905	Device Revision or Replacement	A0705	Battery Problem	09/11/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	09/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	09/11/2022

					CT449	Generators and associated devices			A05	Mechanical Problem		
					CT981	Single use			A05	Mechanical Problem		
					CT983	Surgical invasive			A05	Mechanical Problem		
5576	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT1150	Defibrillators	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT233	Surgical	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2406	Implantable	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2407	Active implantable	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2985	Active	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT3001	Implantable metal	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT314	Electrically powered	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT449	Generators and associated devices	E2104	Electric Shock	A070504	Premature Discharge of Battery		
									A072201	High Impedance		

							F22	Unexpected Diagnostic Intervention	A070504	Premature Discharge of Battery		
					CT981	Single use	E2104	Electric Shock	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2104	Electric Shock	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
5577	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5578	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
									A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
									A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
									A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/02/2023	15/02/2023
5579	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5580	2023	Death	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
									A0709	Device Sensing Problem		
					CT145	Cardiovascular devices	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT233	Surgical	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT2406	Implantable	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT2407	Active implantable	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
									A0709	Device Sensing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT2985	Active	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		

					CT3001	Implantable metal	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT3006	Implantable inorganic material	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT3007	Implantable ceramic	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT314	Electrically powered	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT321	Long-term surgical invasive	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT449	Generators and associated devices	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT981	Single use	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
					CT983	Surgical invasive	E2401	Insufficient Information	A0709	Device Sensing Problem		
							F02	Death	A0709	Device Sensing Problem		
5581	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5582	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
5583	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
5584	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		

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5508	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							A070504	Premature Discharge of Battery	04/07/2023	04/07/2023		
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023		
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023		
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023		
					F1903	Device Implantation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023		
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023		
					E2104	Electric Shock	A070909	Oversensing				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
							A090801	Signal Artifact/Noise				
A1301	Failure to Read Input Signal											
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
		A090801	Signal Artifact/Noise									
		A1301	Failure to Read Input Signal									
F2203	Imaging Required	A070909	Oversensing									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
		A090801	Signal Artifact/Noise									
		A1301	Failure to Read Input Signal									
CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F2203	Imaging Required	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
A090801	Signal Artifact/Noise											
A1301	Failure to Read Input Signal											
CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F2203	Imaging Required	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
A090801	Signal Artifact/Noise											
A1301	Failure to Read Input Signal											
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F2203	Imaging Required	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
A090801	Signal Artifact/Noise											
A1301	Failure to Read Input Signal											
CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F2203	Imaging Required	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
A090801	Signal Artifact/Noise											
A1301	Failure to Read Input Signal											
CT233	Surgical	E2104	Electric Shock	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F2203	Imaging Required	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
A090801	Signal Artifact/Noise											
A1301	Failure to Read Input Signal											
CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A090801	Signal Artifact/Noise							
				A1301	Failure to Read Input Signal							
		F2203	Imaging Required	A070909	Oversensing							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
A090801	Signal Artifact/Noise											
A1301	Failure to Read Input Signal											

CT2407	Active implantable	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		P2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

			F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
			F2203	Imaging Required	A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
CT3001	Implantable metal	E2104	Electric Shock		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F2203	Imaging Required		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
CT3002	Implantable synthetic polymer	E2104	Electric Shock		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F2203	Imaging Required		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
CT3006	Implantable inorganic material	E2104	Electric Shock		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F2203	Imaging Required		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
CT3007	Implantable ceramic	E2104	Electric Shock		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F2203	Imaging Required		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
CT314	Electrically powered	E2104	Electric Shock		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F2203	Imaging Required		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
CT321	Long-term surgical invasive	E2104	Electric Shock		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F2203	Imaging Required		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
CT449	Generators and associated devices	E2104	Electric Shock		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure		A1301 A070909 A071302 A090801	Failure to Read Input Signal Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise			

							F2203	Imaging Required	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT1981	Single use	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F2203	Imaging Required	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT1983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F2203	Imaging Required	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
5589	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		

						CT1150	Defibrillators	E2104	Electric Shock	A1301	Failure to Read Input Signal		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F2203	Imaging Required			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F2203	Imaging Required			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F2203	Imaging Required			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F2203	Imaging Required			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
5592	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock		A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
						CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
						CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
						CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		

5593	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
					CT1258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing								
				A071302	Inappropriate/Inadequate Shock/Stimulation								
				A090801	Signal Artifact/Noise								
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing								
				A071302	Inappropriate/Inadequate Shock/Stimulation								
				A090801	Signal Artifact/Noise								
				A070909	Oversensing								
				A071302	Inappropriate/Inadequate Shock/Stimulation								
				A090801	Signal Artifact/Noise								
CT1266	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing								
				A071302	Inappropriate/Inadequate Shock/Stimulation								
				A090801	Signal Artifact/Noise								
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing								
				A071302	Inappropriate/Inadequate Shock/Stimulation								
				A090801	Signal Artifact/Noise								
				A070909	Oversensing								
				A071302	Inappropriate/Inadequate Shock/Stimulation								
				A090801	Signal Artifact/Noise								
5594	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery								
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery								
CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery								
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery								
CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery								
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery								
CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery								
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery								
CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery								
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery								
CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery								
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery								
CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery								
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery								
5595	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
									A0705	Battery Problem			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
										A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem			
										A070504	Premature Discharge of Battery		

CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
				A1304	Telemetry Discrepancy		
		F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		

							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
							E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F1908	Prolonged Surgery	A1304	Telemetry Discrepancy		
5597	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5598	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016</

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	25/09/2015	25/09/2015
							F1908	Prolonged Surgery	A12	Connection Problem	25/09/2015	25/09/2015
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	25/09/2015	25/09/2015
							F1908	Prolonged Surgery	A12	Connection Problem	25/09/2015	25/09/2015
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	25/09/2015	25/09/2015
							F1908	Prolonged Surgery	A12	Connection Problem	25/09/2015	25/09/2015
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	25/09/2015	25/09/2015
							F1908	Prolonged Surgery	A12	Connection Problem	25/09/2015	25/09/2015
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	25/09/2015	25/09/2015
							F1908	Prolonged Surgery	A12	Connection Problem	25/09/2015	25/09/2015
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	25/09/2015	25/09/2015
							F1908	Prolonged Surgery	A12	Connection Problem	25/09/2015	25/09/2015
5600	2023	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A070910	Undersensing		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
5601	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A02303	Collective Device		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
									A0203	Defective Device		
									A0711	Interrogation Problem		
5602	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT1147	Defibrillators and associated devices	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT1150	Defibrillators	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT141	Electrodes/Leads and associated devices	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT145	Cardiovascular devices	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT233	Surgical	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT2406	Implantable	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT2407	Active implantable	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT258	Implantable defibrillators	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT263	Cardiographs and associated devices	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT2726	Physiological monitoring/measuring devices	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT2985	Active	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT3001	Implantable metal	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT3002	Implantable synthetic polymer	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT3006	Implantable inorganic material	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT3007	Implantable ceramic	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT314	Electrically powered	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT321	Long-term surgical invasive	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT449	Generators and associated devices	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT981	Single use	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
					CT983	Surgical invasive	E060109	Tachycardia	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
5603	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic	A070909	Oversensing		

							Defibrillators	E060104	Bradycardia	A070909	Oversensing						
										A0712	Pacing Problem						
										A090801	Signal Artifact/Noise						
								F1001	Absence of Treatment	A070909	Oversensing						
										A0712	Pacing Problem						
										A090801	Signal Artifact/Noise						
						CT258	Implantable defibrillators	E060104	Bradycardia	A070909	Oversensing						
										A0712	Pacing Problem						
										A090801	Signal Artifact/Noise						
								F1001	Absence of Treatment	A070909	Oversensing						
										A0712	Pacing Problem						
										A090801	Signal Artifact/Noise						
						CT263	Cardiographs and associated devices	E060104	Bradycardia	A070909	Oversensing						
										A0712	Pacing Problem						
										A090801	Signal Artifact/Noise						
								F1001	Absence of Treatment	A070909	Oversensing						
										A0712	Pacing Problem						
										A090801	Signal Artifact/Noise						
CT2866	Implantable cardiac electrical stimulators	E060104	Bradycardia	A070909	Oversensing												
				A0712	Pacing Problem												
				A090801	Signal Artifact/Noise												
		F1001	Absence of Treatment	A070909	Oversensing												
				A0712	Pacing Problem												
				A090801	Signal Artifact/Noise												
5606	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
					CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery							
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
					5607	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
														A071302	Inappropriate/Inadequate Shock/Stimulation		
														A090801	Signal Artifact/Noise		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A090801	Signal Artifact/Noise														
F2203	Imaging Required	A070909	Oversensing														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A090801	Signal Artifact/Noise														
CT1150	Defibrillators	E2104	Electric Shock	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
		F2203	Imaging Required	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
CT258	Implantable defibrillators	E2104	Electric Shock	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
		F2203	Imaging Required	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
		F2203	Imaging Required	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
		F2203	Imaging Required	A070909						Oversensing							
				A071302						Inappropriate/Inadequate Shock/Stimulation							
				A090801						Signal Artifact/Noise							
5608	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022					
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022					
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	15/09/2022	15/09/2022					
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022					
							F1905	Device Revision or Replacement	A0705	Battery Problem	15/09/2022	15/09/2022					
									A070504	Premature Discharge of Battery	15/09/2022	15/09/2022					
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/09/2022	15/09/2022					
											A070504	Premature Discharge of Battery	15/09/2022	15/09/2022			
											A0705	Battery Problem	15/09/2022	15/09/2022			
					CT1147	Defibrillators and associated devices	E2403		A070504	Premature Discharge of Battery	15/09/2022	15/09/2022					
											A0705	Battery Problem	15/09/2022	15/09/2022			
											A0705	Battery Problem	15/09/2022	15/09/2022			
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2022	15/09/2022						
										A0705	Battery Problem	15/09/2022	15/09/2022				
										A070504	Premature Discharge of Battery	15/09/2022	15/09/2022				

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5612	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
5613	2023	All other reportable incidents			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/11/2022	16/11/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/11/2022	16/11/2022
									A0705	Battery Problem	16/11/2022	16/11/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/11/2022	16/11/2022
									A0705	Battery Problem	16/11/2022	16/11/2022
									A070504	Premature Discharge of Battery	16/11/2022	16/11/2022
5614	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5615	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5616	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5617	2023	All other reportable incidents			CT258	Implantable defibrillators	E0601	Arrhythmia	A070504	Premature Discharge of Battery		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
5618	2023	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
5619	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
									A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
									A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
									A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
									A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
									A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
									A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023

						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/01/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	02/01/2023	02/01/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/01/2023	02/01/2023
5620	2023	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F1903	Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F23	Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F1903	Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F23	Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F1903	Device Explanation	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F2203	Imaging Required	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F23	Unexpected Medical Intervention	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	01/12/2022	01/12/2022
								A070909	Overensing	01/12/2022	01/12/2022
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/12/2022	01/12/2022
								A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
						F10	Inadequate/Inappropriate Treatment or Diagnostic	A0709	Device Sensing Problem	01/12/2022	01/12/2022

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					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070504	Premature Discharge of Battery			
									A1301	Failure to Read Input Signal			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070504	Premature Discharge of Battery			
									A1301	Failure to Read Input Signal			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070504	Premature Discharge of Battery			
									A1301	Failure to Read Input Signal			
5624	2023		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event			
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event			
5625	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0119	Loss of Consciousness	A070909	Oversensing			
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
						E011903	Syncope/Fainting	A070909	Oversensing				
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing				
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
						F2203	Imaging Required	A070909	Oversensing				
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
						F2306	Resuscitation	A070909	Oversensing				
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
					CT1150	Defibrillators	E0119	Loss of Consciousness	A070909	Oversensing			
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
						E011903	Syncope/Fainting	A070909	Oversensing				
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing				
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
						F2203	Imaging Required	A070909	Oversensing				
									A071201	Failure to Convert Rhythm			
									A072201	High Impedance			
						F2306	Resuscitation	A070909	Oversensing				
									A071201	Failure to Convert Rhythm			

					CT258	Implantable defibrillators	E0119	Loss of Consciousness	A072201 A070909 A071201 A072201	High Impedance Oversensing Failure to Convert Rhythm High Impedance		
							E011903	Syncope/Fainting	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F2203	Imaging Required	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F2306	Resuscitation	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
					CT263	Cardiographs and associated devices	E0119	Loss of Consciousness	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							E011903	Syncope/Fainting	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F2203	Imaging Required	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F2306	Resuscitation	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E0119	Loss of Consciousness	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							E011903	Syncope/Fainting	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F2203	Imaging Required	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
							F2306	Resuscitation	A070909 A071201 A072201	Oversensing Failure to Convert Rhythm High Impedance		
5626	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
5627	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
5628	2023		37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0112	Dizziness	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
							E0601	Arrhythmia	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
							F1901	Additional Surgery	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
					CT1150	Defibrillators	E0112	Dizziness	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
							E0601	Arrhythmia	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
							F1901	Additional Surgery	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
					CT141	Electrodes/Leads and associated devices	E0112	Dizziness	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
							E0601	Arrhythmia	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
							F1901	Additional Surgery	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
					CT145	Cardiovascular devices	E0112	Dizziness	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023
							E0601	Arrhythmia	A070909 A071204	Oversensing No Pacing	13/03/2023 13/03/2023	13/03/2023 13/03/2023

CT233	Surgical	F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
		E0112	Dizziness	A071204	No Pacing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A070909	Oversensing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A071204	No Pacing	13/03/2023	13/03/2023
CT2406	Implantable	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT2407	Active implantable	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT258	Implantable defibrillators	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT2727	Active implant devices/ancillaries	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT2750	Implantable cardiac electrical stimulators and associated devices	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT2866	Implantable cardiac electrical stimulators	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT2985	Active	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT3001	Implantable metal	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT3002	Implantable synthetic polymer	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT3006	Implantable inorganic material	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT3007	Implantable ceramic	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT314	Electrically powered	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT321	Long-term surgical invasive	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A071204	No Pacing	13/03/2023	13/03/2023
		F1901	Additional Surgery	A070909	Oversensing	13/03/2023	13/03/2023
				A071204	No Pacing	13/03/2023	13/03/2023
CT449	Generators and associated devices	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
		E0601	Arrhythmia	A070909	Oversensing	13/03/2023	13/03/2023

							F1901	Additional Surgery	A071204	No Pacing	A070909	Oversensing	13/03/2023	13/03/2023
									A071204	No Pacing	A070909	Oversensing	13/03/2023	13/03/2023
						CT981		Single use	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
									A071204	No Pacing	A070909	Oversensing	13/03/2023	13/03/2023
							E0601	Arrhythmia	A070909	Oversensing	A071204	No Pacing	13/03/2023	13/03/2023
									A071204	No Pacing	A070909	Oversensing	13/03/2023	13/03/2023
							F1901	Additional Surgery	A070909	Oversensing	A071204	No Pacing	13/03/2023	13/03/2023
									A071204	No Pacing	A070909	Oversensing	13/03/2023	13/03/2023
						CT983		Surgical invasive	E0112	Dizziness	A070909	Oversensing	13/03/2023	13/03/2023
									A071204	No Pacing	A070909	Oversensing	13/03/2023	13/03/2023
							E0601	Arrhythmia	A070909	Oversensing	A071204	No Pacing	13/03/2023	13/03/2023
									A071204	No Pacing	A070909	Oversensing	13/03/2023	13/03/2023
							F1901	Additional Surgery	A070909	Oversensing	A071204	No Pacing	13/03/2023	13/03/2023
									A071204	No Pacing	A070909	Oversensing	13/03/2023	13/03/2023
5629	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	A1102	Application Program Problem		
									A23	Use of Device Problem				
5630	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	F08	Hospitalization or Prolonged Hospitalization		
									A072201	High Impedance	F2203	Imaging Required		
									A072201	High Impedance				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	F08	Hospitalization or Prolonged Hospitalization		
									A072201	High Impedance	F2203	Imaging Required		
									A072201	High Impedance				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	F08	Hospitalization or Prolonged Hospitalization		
									A072201	High Impedance	F2203	Imaging Required		
									A072201	High Impedance				
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	F08	Hospitalization or Prolonged Hospitalization		
									A072201	High Impedance	F2203	Imaging Required		
									A072201	High Impedance				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	F08	Hospitalization or Prolonged Hospitalization		
									A072201	High Impedance	F2203	Imaging Required		
									A072201	High Impedance				
5631	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1705	Burning Sensation	A0709	Device Sensing Problem	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A12	Connection Problem		
									A0709	Device Sensing Problem	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A12	Connection Problem		
							E2104	Electric Shock	A0709	Device Sensing Problem	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A12	Connection Problem		
									A12	Connection Problem				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A12	Connection Problem		
									A12	Connection Problem				
							F2203	Imaging Required	A0709	Device Sensing Problem	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A12	Connection Problem		
									A12	Connection Problem				
					CT1147	Defibrillators and associated devices	E1705	Burning Sensation	A0709	Device Sensing Problem	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A12	Connection Problem		
									A12	Connection Problem				
							E2104	Electric Shock	A0709	Device Sensing Problem	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A12	Connection Problem		
									A12	Connection Problem				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A12	Connection Problem		
									A12	Connection Problem				
							F2203	Imaging Required	A0709	Device Sensing Problem				

CT1150	Defibrillators	E1705	Burning Sensation	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		
CT141	Electrodes/Leads and associated devices	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT145	Cardiovascular devices	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT233	Surgical	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT2406	Implantable	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT2407	Active implantable	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		

					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
				F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	
					A12	Connection Problem		
					A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT258	Implantable defibrillators	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT263	Cardiographs and associated devices	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT2726	Physiological monitoring/measuring devices	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT2727	Active implant devices/ancillaries	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT2750	Implantable cardiac electrical stimulators and associated devices	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		

CT2866	Implantable cardiac electrical stimulators	E1705	Burning Sensation	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E1705	Burning Sensation	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E1705	Burning Sensation	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E1705	Burning Sensation	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E1705	Burning Sensation	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E1705	Burning Sensation	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

9632	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
								A070909	Oversensing					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
								A12	Connection Problem					
							F2203	Imaging Required	A0709	Device Sensing Problem				
								A070909	Oversensing					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
								A12	Connection Problem					
							E1705	Burning Sensation	A0709	Device Sensing Problem				
								A070909	Oversensing					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
								A12	Connection Problem					
							E2104	Electric Shock	A0709	Device Sensing Problem				
								A070909	Oversensing					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
								A12	Connection Problem					
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem				
								A070909	Oversensing					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
								A12	Connection Problem					
							F2203	Imaging Required	A0709	Device Sensing Problem				
								A070909	Oversensing					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
								A12	Connection Problem					
							CT321	Long-term surgical invasive	E1705	Burning Sensation	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									E2104	Electric Shock	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									F2203	Imaging Required	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
							CT449	Generators and associated devices	E1705	Burning Sensation	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									E2104	Electric Shock	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									F2203	Imaging Required	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
							CT981	Single use	E1705	Burning Sensation	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									E2104	Electric Shock	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
									F2203	Imaging Required	A0709	Device Sensing Problem		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A12	Connection Problem		
							CT983	Surgical invasive	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing									
				A071302	Inappropriate/Inadequate Shock/Stimulation									
				A12	Connection Problem									
		E2104	Electric Shock	A0709	Device Sensing Problem									
				A070909	Oversensing									
				A071302	Inappropriate/Inadequate Shock/Stimulation									
				A12	Connection Problem									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem									
				A070909	Oversensing									
				A071302	Inappropriate/Inadequate Shock/Stimulation									
				A12	Connection Problem									
		F2203	Imaging Required	A0709	Device Sensing Problem									
				A070909	Oversensing									
				A071302	Inappropriate/Inadequate Shock/Stimulation									
				A12	Connection Problem									
		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem									

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56.98	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
								A0705	Battery Problem								
								A070504	Premature Discharge of Battery								
					F26	No Health Consequences or Impact	A0705	Battery Problem									
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery							
								A070504	Battery Problem								
								A0705	Premature Discharge of Battery								
								A070504	Premature Discharge of Battery								
								A070504	Premature Discharge of Battery								
								A070504	Premature Discharge of Battery								
					CT1010	Cardiovascular physiology analysis/mapping devices	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT1147	Defibrillators and associated devices	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT1150	Defibrillators	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT1141	Electrodes/Leads and associated devices	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT1145	Cardiovascular devices	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT233	Surgical	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT2406	Implantable	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT2407	Active implantable	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT258	Implantable defibrillators	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT263	Cardiographs and associated devices	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT2726	Physiological monitoring/measuring devices	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT2727	Active implant devices/ancillaries	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT2866	Implantable cardiac electrical stimulators	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT2985	Active	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT3001	Implantable metal	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT3002	Implantable synthetic polymer	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT3006	Implantable inorganic material	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT3007	Implantable ceramic	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT314	Electrically powered	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT321	Long-term surgical invasive	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT449	Generators and associated devices	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT981	Single use	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					CT983	Surgical invasive	E2330	Pain	A010402	Migration	25/01/2022	25/01/2022					
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	25/01/2022	25/01/2022					
							F1905	Device Revision or Replacement	A010402	Migration	25/01/2022	25/01/2022					
					56.99	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
												F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
														A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
														A0908	Incorrect, Inadequate or Imprecise Result or Readings		
												F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
														A0908	Incorrect, Inadequate or Imprecise Result or Readings		

					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A070504	Premature Discharge of Battery			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A070504	Premature Discharge of Battery			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A070504	Premature Discharge of Battery			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
5640	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
							F23	Unexpected Medical Intervention	A070504	Premature Discharge of Battery			
5641	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			

							F26	No Health Consequences or Impact	A072201	High Impedance		
					C1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	High Impedance		
					C1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	Incorrect, Inadequate or Imprecise Result or Readings		
									A0908	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5642	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
5643	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5644	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2022	22/09/2022
5645	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	26/10/2022	26/10/2022
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
							F1903	Device Explanation	A0705	Battery Problem	26/10/2022	26/10/2022
									A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
5646	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		

					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5647	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2203	Imaging Required	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2104	Electric Shock	A0709	Device Sensing Problem		

				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2407	Active implantable	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3001	Implantable metal	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Overensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			

							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
					CT2666	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/04/2023	14/04/2023
9552	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT233	Surgical	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT2406	Implantable	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT2407	Active implantable	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		

					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
									A1301	Failure to Read Input Signal									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing									
							A071302	Inappropriate/Inadequate Shock/Stimulation											
							A090801	Signal Artifact/Noise											
							A1301	Failure to Read Input Signal											
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
									A1301	Failure to Read Input Signal									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing									
							A071302	Inappropriate/Inadequate Shock/Stimulation											
							A090801	Signal Artifact/Noise											
							A1301	Failure to Read Input Signal											
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise									
									A1301	Failure to Read Input Signal									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing									
							A071302	Inappropriate/Inadequate Shock/Stimulation											
							A090801	Signal Artifact/Noise											
							A1301	Failure to Read Input Signal											
5653	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A07	Electrical /Electronic Property Problem									
									A071301	Failure to Deliver Shock/Stimulation									
									F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem							
									A071301	Failure to Deliver Shock/Stimulation									
							F1203	Life Threatening Illness or Injury	A07	Electrical /Electronic Property Problem									
							A071301	Failure to Deliver Shock/Stimulation											
							F23	Unexpected Medical Intervention	A07	Electrical /Electronic Property Problem									
							A071301	Failure to Deliver Shock/Stimulation											
					CT1150	Defibrillators	E060109	Tachycardia	A07	Electrical /Electronic Property Problem									
									A071301	Failure to Deliver Shock/Stimulation									
									F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem							
									A071301	Failure to Deliver Shock/Stimulation									
							F1203	Life Threatening Illness or Injury	A07	Electrical /Electronic Property Problem									
							A071301	Failure to Deliver Shock/Stimulation											
							F23	Unexpected Medical Intervention	A07	Electrical /Electronic Property Problem									
							A071301	Failure to Deliver Shock/Stimulation											
					CT258	Implantable defibrillators	E060109	Tachycardia	A07	Electrical /Electronic Property Problem									
									A071301	Failure to Deliver Shock/Stimulation									
									F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem							
									A071301	Failure to Deliver Shock/Stimulation									
							F1203	Life Threatening Illness or Injury	A07	Electrical /Electronic Property Problem									
							A071301	Failure to Deliver Shock/Stimulation											
							F23	Unexpected Medical Intervention	A07	Electrical /Electronic Property Problem									
							A071301	Failure to Deliver Shock/Stimulation											
CT263	Cardiographs and associated devices	E060109	Tachycardia	A07	Electrical /Electronic Property Problem														
				A071301	Failure to Deliver Shock/Stimulation														
				F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem												
				A071301	Failure to Deliver Shock/Stimulation														
		F1203	Life Threatening Illness or Injury	A07	Electrical /Electronic Property Problem														
		A071301	Failure to Deliver Shock/Stimulation																
		F23	Unexpected Medical Intervention	A07	Electrical /Electronic Property Problem														
		A071301	Failure to Deliver Shock/Stimulation																
CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A07	Electrical /Electronic Property Problem														
				A071301	Failure to Deliver Shock/Stimulation														
				F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem												
				A071301	Failure to Deliver Shock/Stimulation														
		F1203	Life Threatening Illness or Injury	A07	Electrical /Electronic Property Problem														
		A071301	Failure to Deliver Shock/Stimulation																
		F23	Unexpected Medical Intervention	A07	Electrical /Electronic Property Problem														
		A071301	Failure to Deliver Shock/Stimulation																
5654	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A1107	Data Problem									
									A0712	Pacing Problem									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation									
							A1107	Data Problem											
							CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem							
											A071302	Inappropriate/Inadequate Shock/Stimulation							
					A1107	Data Problem													
					A0712	Pacing Problem													
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A071302	Inappropriate/Inadequate Shock/Stimulation									
					A1107	Data Problem													
					CT2866	Implantable cardiac electrical stimulators			E2104	Electric Shock	A0712	Pacing Problem							
											A071302	Inappropriate/Inadequate Shock/Stimulation							
							A1107	Data Problem											
							A0712	Pacing Problem											
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation									
							A1107	Data Problem											
							5655	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
																A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation													
					A090801	Signal Artifact/Noise													
					F08	Hospitalization or Prolonged Hospitalization								A070909	Oversensing				
					A070910	Undersensing													
A071302	Inappropriate/Inadequate Shock/Stimulation																		
A071302	Inappropriate/Inadequate Shock/Stimulation																		

					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A079081 A079098 A07910 A071302 A090801	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F2203	Imaging Required	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT1147	Defibrillators and associated devices	E2104	Electric Shock	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
					F08	Hospitalization or Prolonged Hospitalization	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F2203	Imaging Required	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT1150	Defibrillators	E2104	Electric Shock	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
					F08	Hospitalization or Prolonged Hospitalization	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F2203	Imaging Required	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
					F08	Hospitalization or Prolonged Hospitalization	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F2203	Imaging Required	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT145	Cardiovascular devices	E2104	Electric Shock	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
					F08	Hospitalization or Prolonged Hospitalization	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A079099 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			

		F2203	Imaging Required	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2406	Implantable	F1905	Device Revision or Replacement	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	F2203	Imaging Required	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A070910	Undersensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		

					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
			F1905	Device Revision or Replacement	A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
			F2203	Imaging Required	A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F2203	Imaging Required		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F2203	Imaging Required		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F2203	Imaging Required		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					A070910	Undersensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F1905	Device Revision or Replacement		A070909	Oversensing		
					A070910	Undersensing		

CT2985	Active	P2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
CT3001	Implantable metal	P2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
CT3002	Implantable synthetic polymer	P2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
CT3006	Implantable inorganic material	P2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
CT3007	Implantable ceramic	P2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A070909	Oversensing		
				A070910	Undersensing		

					F08	Hospitalization or Prolonged Hospitalization	A090801 A070909 A070910 A071302 A090801	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F2203	Imaging Required	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT314	Electrically powered	E2104	Electric Shock	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
					F08	Hospitalization or Prolonged Hospitalization	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F2203	Imaging Required	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
					F08	Hospitalization or Prolonged Hospitalization	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F2203	Imaging Required	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT449	Generators and associated devices	E2104	Electric Shock	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
					F08	Hospitalization or Prolonged Hospitalization	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F1905	Device Revision or Replacement	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F2203	Imaging Required	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
				CT981	Single use	E2104	Electric Shock	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
					F08	Hospitalization or Prolonged Hospitalization	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A090801	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			

							F1905	Device Revision or Replacement	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F1905	Device Revision or Replacement	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
3656	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/03/2023	27/03/2023
									A070504	Premature Discharge of Battery	27/03/2023	27/03/2023
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/03/2023	27/03/2023

[illegible]

5659	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					F26	No Health Consequences or Impact	A072201	High Impedance				
5660	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise				

					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
5661	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A070909	Oversensing		
5662	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
							F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem		
									A051201	Device Dislodged or Dislocated		
							F1905	Device Revision or Replacement	A0722	Impedance Problem		
									A051201	Device Dislodged or Dislocated		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
							F1905	Device Revision or Replacement	A0722	Impedance Problem		
									A051201	Device Dislodged or Dislocated		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		
							F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
							F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem		
									A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		

			F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated	
					A0722	Impedance Problem	
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
		F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem		
				A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
				A0722	Impedance Problem		
		F08	Hospitalization or Prolonged Hospitalization	A051201	Device Dislodged or Dislocated		

							F1905	Device Revision or Replacement	A0722	Impedance Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		
					CT314	Electrically powered			A051201	Device Dislodged or Dislocated		
							F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem		
							F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
							F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem		
							F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
							F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem		
							F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
							F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem		
							F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
							F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem		
							F1905	Device Revision or Replacement	A051201	Device Dislodged or Dislocated		
									A0722	Impedance Problem		
5663	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
							P26	No Health Consequences or Impact	A0722	Impedance Problem		
5664	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
							P23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							P23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
							P23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
					CT1145	Cardiovascular devices	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							P23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
					CT233	Surgical	E060109	Tachycardia	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
							P23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
					CT2406	Implantable	E060109	Tachycardia	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Deliver Shock/Stimulation		

		F1001	Absence of Treatment	A0709	Device Sensing Problem		
		A071301		A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
		F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
CT2407	Active implantable	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2985	Active	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3001	Implantable metal	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3002	Implantable synthetic polymer	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
		F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3006	Implantable inorganic material	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic	A0709	Device Sensing Problem		

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9667	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
					F26	No Health Consequences or Impact	A072201	High Impedance									
					9668	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery							
F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery														
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery							
F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery														
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504						Premature Discharge of Battery							
F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery														
9669	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					
					F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023							
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023					

						CT981	Single use	F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023
						CT983	Surgical invasive	F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023	04/04/2023
5670	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
					CT1258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
					CT1263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
					CT12866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
5671	2023	All other reportable incidents	47940	Triple-chamber implantable defibrillator	CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
								F24	Insufficient Health Impact Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
										A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
					CT1258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
								F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
					CT12866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
								F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery	06/07/2023	06/07/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/07/2023	06/07/2023
5672	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2104	Electric Shock	A070909	Overensing		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators		F10	Electric Shock	A070909	Overensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Electric Shock	A070909	Overensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1258	Implantable defibrillators		E2104	Electric Shock	A070909	Overensing		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Overensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1263	Cardiographs and associated devices		E2104	Electric Shock	A070909	Overensing		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT12866	Implantable cardiac electrical stimulators		E2104	Electric Shock	A070909	Overensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
5673	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices		E060109	Tachycardia	A0709	Device Sensing Problem		
								F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
										A0709	Device Sensing Problem		
								F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
										A0709	Device Sensing Problem		
					CT1150	Defibrillators		E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
								F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
										A0709	Device Sensing Problem		
								F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
										A071301	Failure to Deliver Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices		E060109	Tachycardia	A0709	Device Sensing Problem		
								F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
										A0709	Device Sensing Problem		
								F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
										A071301	Failure to Deliver Shock/Stimulation		
					CT145	Cardiovascular devices		E060109	Tachycardia	A0709	Device Sensing Problem		
								F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
										A0709	Device Sensing Problem		
										A071301	Failure to Deliver Shock/Stimulation		

		F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
CT233	Surgical	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
CT2406	Implantable	F1203	Life Threatening illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
		E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
				A0709	Device Sensing Problem		
CT2407	Active implantable	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2727	Active implant devices/ancillaries	F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT2985	Active	F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3001	Implantable metal	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3002	Implantable synthetic polymer	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3006	Implantable inorganic material	F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT3007	Implantable ceramic	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT314	Electrically powered	E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT321	Long-term surgical invasive	F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
CT449	Generators and associated devices	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		
		E060109	Tachycardia	A0709	Device Sensing Problem		
				A071301	Failure to Deliver Shock/Stimulation		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT266	implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8678	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
						F26	No Health Consequences or Impact		A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		

		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		

						F26	No Health Consequences or Impact	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal				
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal				
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal				
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal				
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A0709 A070909 A090801 A1301	Device Sensing Problem Oversensing Signal Artifact/Noise Failure to Read Input Signal				
5679	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise			
						F26	No Health Consequences or Impact	A070909 A090801	Oversensing Signal Artifact/Noise				
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			

								F26	No Health Consequences or Impact	A079099 A090801	Oversensing Signal Artifact/Noise		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A090801	Oversensing Signal Artifact/Noise		
							F26	No Health Consequences or Impact		A079099 A090801	Oversensing Signal Artifact/Noise		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A090801	Oversensing Signal Artifact/Noise		
							F26	No Health Consequences or Impact		A079099 A090801	Oversensing Signal Artifact/Noise		
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A090801	Oversensing Signal Artifact/Noise		
							F26	No Health Consequences or Impact		A079099 A090801	Oversensing Signal Artifact/Noise		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A090801	Oversensing Signal Artifact/Noise		
							F26	No Health Consequences or Impact		A079099 A090801	Oversensing Signal Artifact/Noise		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A090801	Oversensing Signal Artifact/Noise		
							F26	No Health Consequences or Impact		A079099 A090801	Oversensing Signal Artifact/Noise		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A090801	Oversensing Signal Artifact/Noise		
							F26	No Health Consequences or Impact		A079099 A090801	Oversensing Signal Artifact/Noise		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A090801	Oversensing Signal Artifact/Noise		
							F26	No Health Consequences or Impact		A079099 A090801	Oversensing Signal Artifact/Noise		
5680	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F08	Hospitalization or Prolonged Hospitalization			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F1905	Device Revision or Replacement			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F08	Hospitalization or Prolonged Hospitalization			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F1905	Device Revision or Replacement			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F08	Hospitalization or Prolonged Hospitalization			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F1905	Device Revision or Replacement			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F08	Hospitalization or Prolonged Hospitalization			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F1905	Device Revision or Replacement			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F08	Hospitalization or Prolonged Hospitalization			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F1905	Device Revision or Replacement			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F08	Hospitalization or Prolonged Hospitalization			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F1905	Device Revision or Replacement			A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions		A079099 A180103 A180104	Oversensing Device Contamination with Body Fluid Device Contamination with Chemical or Other Material	03/02/2023 03/02/2023 03/02/2023	03/02/2023 03/02/2023 03/02/2023
						F08	Hospitalization or Prolonged Hospitalization			A079099	Oversensing	03/02/2023	03/02/2023

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					CT2407	Active implantable	E2330 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT258	Implantable defibrillators	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT263	Cardiographs and associated devices	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT2726	Physiological monitoring/measuring devices	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT2727	Active implant devices/ancillaries	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT2866	Implantable cardiac electrical stimulators	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT2985	Active	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT3001	Implantable metal	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT3002	Implantable synthetic polymer	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT3006	Implantable inorganic material	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT3007	Implantable ceramic	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT314	Electrically powered	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT321	Long-term surgical invasive	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT449	Generators and associated devices	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT981	Single use	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
					CT983	Surgical invasive	E2330 F08 F1905	Pain Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A010402 A010402 A010402	Migration Migration Migration	25/01/2022 25/01/2022 25/01/2022	25/01/2022 25/01/2022 25/01/2022
5682	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403 F02	No Clinical Signs, Symptoms or Conditions Death	A070602 A070603	Delayed Charge Time Failure to Charge		
					CT258	Implantable defibrillators	E2403 F02	No Clinical Signs, Symptoms or Conditions Death	A070602 A070603	Delayed Charge Time Failure to Charge		
					CT2866	Implantable cardiac electrical stimulators	E2403 F02	No Clinical Signs, Symptoms or Conditions Death	A070602 A070603	Delayed Charge Time Failure to Charge		
5683	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2104 F10	Electric Shock Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		

					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT233	Surgical	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2406	Implantable	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2407	Active implantable	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2868	Implantable cardiac electrical stimulators	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT2985	Active	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT3008	Implantable inorganic material	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
CT3007	Implantable ceramic	E2104	Electric Shock		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Overensensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A071302 A090801 A1301	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT233	Surgical	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2406	Implantable	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2407	Active implantable	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2727	Active implant devices/rancilians	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT314	Electrically powered	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT981	Single use	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
					CT983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
5686	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A1107	Oversensing Data Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A1107	Oversensing Data Problem		
5687	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A0705 A070504	Noise, Audible Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A0705 A070504	Noise, Audible Battery Problem Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A0705 A070504	Noise, Audible Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A0705 A070504	Noise, Audible Battery Problem Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A0705 A070504	Noise, Audible Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0508 A0705	Noise, Audible Battery Problem		

CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		
		F26	No Health Consequences or Impact	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A070504	Premature Discharge of Battery		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A070504	Premature Discharge of Battery		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A070504	Premature Discharge of Battery		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A070504	Premature Discharge of Battery		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A070504	Premature Discharge of Battery		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
				A070504	Premature Discharge of Battery		
		F26	No Health Consequences or Impact	A0508	Noise, Audible		
				A070504	Premature Discharge of Battery		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
				A0705	Battery Problem		
		F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				A0508	Noise, Audible		

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							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
5691	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
5692	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing	20/04/2023	20/04/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302 A070909	Inappropriate/Inadequate Shock/Stimulation Oversensing	20/04/2023	20/04/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	20/04/2023	20/04/2023
5693	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT1150	Defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT1141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT1145	Cardiovascular devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT233	Surgical	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT2406	Implantable	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT2407	Active implantable	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT2985	Active	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT3001	Implantable metal	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT3006	Implantable inorganic material	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT3007	Implantable ceramic	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT314	Electrically powered	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT321	Long-term surgical invasive	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT449	Generators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT981	Single use	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT983	Surgical invasive	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
5694	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT233	Surgical	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT2406	Implantable	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT2407	Active implantable	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT258	Implantable defibrillators	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT2985	Active	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT3001	Implantable metal	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT3006	Implantable inorganic material	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT3007	Implantable ceramic	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT314	Electrically powered	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT321	Long-term surgical invasive	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT449	Generators and associated devices	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT981	Single use	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
					CT983	Surgical invasive	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation	
5695	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201	Overensing Pacing Problem High Impedance	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A0712 A072201	Failure to Read Input Signal Overensing Pacing Problem High Impedance	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Overensing Pacing Problem High Impedance Failure to Read Input Signal	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201	Overensing Pacing Problem High Impedance	

CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A072201	High Impedance		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A072201	High Impedance		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A072201	High Impedance		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A072201	High Impedance		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
				A072201	High Impedance		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		

CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
				A1301	Failure to Read Input Signal							
				A070909	Oversensing							
				A0712	Pacing Problem							
				A072201	High Impedance							
9696	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

					CT1150	Defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5697	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explantation	A160601	Premature Elective Replacement Indicator		
5698	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
5699	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic	A070909	Oversensing		

									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing			
											A071302	Inappropriate/Inadequate Shock/Stimulation		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
											A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing			
											A071302	Inappropriate/Inadequate Shock/Stimulation		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
											A071302	Inappropriate/Inadequate Shock/Stimulation		
5708	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
											A071204	No Pacing		
									F23	Unexpected Medical Intervention	A070909	Oversensing		
											A071204	No Pacing		
5709	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5710	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023	09/03/2023
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023

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						F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
								A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/03/2023	09/03/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/03/2023	09/03/2023
9711	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
9712	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem	
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem	
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem	
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
						F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
								A0722	Impedance Problem		
								A090804	False Positive Result		
								A090805	Incorrect Measurement		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem	
								A0722	Impedance Problem		

				F08	Hospitalization or Prolonged Hospitalization	A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
				F12	Serious Injury/ Illness/ Impairment	A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
CT233	Surgical			E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
				F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
				F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
CT2406	Implantable			E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
				F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
CT2407	Active implantable			E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
				F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
CT258	Implantable defibrillators			E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
				F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
				F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
CT2727	Active implant devices/ancillaries			E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
				F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			
						A0713	Defibrillation/Stimulation Problem			
						A0722	Impedance Problem			
						A090804	False Positive Result			
						A090805	Incorrect Measurement			

		F1905	Device Revision or Replacement	A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
				A090805	Incorrect Measurement		

CT3007	Implantable ceramic	F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
		F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		
				A0713	Defibrillation/Stimulation Problem		
				A0722	Impedance Problem		
				A090804	False Positive Result		
				A090805	Incorrect Measurement		

									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
						F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem			
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
						F12	Serious Injury/Illness/ Impairment	A0713	Defibrillation/Stimulation Problem			
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
						F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem			
									A0722	Impedance Problem		
									A090804	False Positive Result		
									A090805	Incorrect Measurement		
5713	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/07/2023	24/07/2023
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F1905	Device Revision or Replacement	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/07/2023	24/07/2023
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F1905	Device Revision or Replacement	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/07/2023	24/07/2023
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F1905	Device Revision or Replacement	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/07/2023	24/07/2023
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F1905	Device Revision or Replacement	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	24/07/2023	24/07/2023
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
						F1905	Device Revision or Replacement	A0705	Battery Problem	24/07/2023	24/07/2023	
									A070504	Premature Discharge of Battery	24/07/2023	24/07/2023
5714	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal			
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal			
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal			
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal			
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal			
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal			
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal			

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A070909	Oversensing		
				A0712	Pacing Problem		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A0712	Pacing Problem		

6717	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							E2104	Electric Shock	A0712	Pacing Problem		
									A070909	Device Sensing Problem		
									A070909	Oversensing		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	It inappropriate/inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							E2330	Pain	A071302	It inappropriate/inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	It inappropriate/inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	It inappropriate/inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	It inappropriate/inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	It inappropriate/inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	It inappropriate/inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	It inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	It inappropriate/inadequate Shock/Stimulation		
					CT233	Surgical	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	It inappropriate/inadequate Shock/Stimulation		
							E2330	Pain	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A070909	Oversensing		

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					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem			
					A070909	Overensing			
		F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
					A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2330	Pain		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem			
					A070909	Overensing			
		F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
					A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2330	Pain		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem			
					A070909	Overensing			
		F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
					A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
CT2985	Active	E2104	Electric Shock		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2330	Pain		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem			
					A070909	Overensing			
		F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
					A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3001	Implantable metal	E2104	Electric Shock		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2330	Pain		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem			
					A070909	Overensing			
		F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
					A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3002	Implantable synthetic polymer	E2104	Electric Shock		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2330	Pain		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F08	Hospitalization or Prolonged Hospitalization		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem			
					A070909	Overensing			
		F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
					A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
CT3006	Implantable inorganic material	E2104	Electric Shock		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
		E2330	Pain		A0709	Device Sensing Problem			
					A070909	Overensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			

		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F2203	Imaging Required	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
				E2330	Pain	A070909	Oversensing		
A071302	Inappropriate/Inadequate Shock/Stimulation								
A0709	Device Sensing Problem								
F08	Hospitalization or Prolonged Hospitalization			A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
F2203	Imaging Required			A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
		A0709	Device Sensing Problem						
CT314	Electrically powered	E2104	Electric Shock	A0709	Device Sensing Problem				
		E2330	Pain	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F2203	Imaging Required	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
A0709	Device Sensing Problem								
CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem				
		E2330	Pain	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F2203	Imaging Required	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
A0709	Device Sensing Problem								
CT449	Generators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem				
		E2330	Pain	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F2203	Imaging Required	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
A0709	Device Sensing Problem								
CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem				
		E2330	Pain	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F2203	Imaging Required	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
A0709	Device Sensing Problem								
CT983	Surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem				
		E2330	Pain	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A0709	Device Sensing Problem				
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
A0709	Device Sensing Problem								

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						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
5727	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A0712	Pacing Problem	
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A0712	Pacing Problem	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A0712	Pacing Problem	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A0712	Pacing Problem	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A0712	Pacing Problem	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
							F26	No Health Consequences or Impact	A0712	Pacing Problem	
								A070909	Oversensing		

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5729	2023		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2107	Failure of Implant	A0203	Defective Device		
							A07		A07	Electrical /Electronic Property Problem		
							F07	Exacerbation of Existing Condition	A1910	Electrical Power Problem		
									A0203	Defective Device		
									A07	Electrical /Electronic Property Problem		
							F15	Recognized Device or Procedural Complication	A1910	Electrical Power Problem		
									A0203	Defective Device		
									A07	Electrical /Electronic Property Problem		
							F16	Reduction in Life Expectancy	A1910	Electrical Power Problem		
									A0203	Defective Device		
									A07	Electrical /Electronic Property Problem		
									A1910	Electrical Power Problem		
5730	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5731	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
									A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
									A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
									A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
									A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
									A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
									A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
5732	2023		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2023	20/06/2023
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
		F11	Non-Serious Injury/ Illness/ Impairment	A1301	Failure to Read Input Signal			
				A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT145	Cardiovascular devices	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F2203	Imaging Required	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
CT233	Surgical	E2104	Electric Shock	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
				A070909	Oversensing			
				A071302	Inappropriate/Inadequate Shock/Stimulation			
				A090801	Signal Artifact/Noise			
				A1301	Failure to Read Input Signal			
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem			
				A070909	Oversensing			

				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2406	Implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2407	Active implantable	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem		

					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F2203	Imaging Required	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2727	Active Implant devices/ancillaries	E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F2203	Imaging Required	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F2203	Imaging Required	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F2203	Imaging Required	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2865	Active	E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		

		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem					
				A070909	Oversensing					
				A071302	Inappropriate/Inadequate Shock/Stimulation					
				A090801	Signal Artifact/Noise					
				A1301	Failure to Read Input Signal					
		F2203	Imaging Required	A0709	Device Sensing Problem					
				A070909	Oversensing					
				A071302	Inappropriate/Inadequate Shock/Stimulation					
				A090801	Signal Artifact/Noise					
				A1301	Failure to Read Input Signal					
		CT3001	Implantable metal	E2104	Electric Shock	A1301	Failure to Read Input Signal			
						A0709	Device Sensing Problem			
						A070909	Oversensing			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
			F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal				
					A0709	Device Sensing Problem				
					A070909	Oversensing				
					A071302	Inappropriate/Inadequate Shock/Stimulation				
A090801	Signal Artifact/Noise									
F11	Non-Serious Injury/ Illness/ Impairment		A1301	Failure to Read Input Signal						
			A0709	Device Sensing Problem						
			A070909	Oversensing						
			A071302	Inappropriate/Inadequate Shock/Stimulation						
		A090801	Signal Artifact/Noise							
F2203	Imaging Required	A1301	Failure to Read Input Signal							
		A0709	Device Sensing Problem							
		A070909	Oversensing							
		A071302	Inappropriate/Inadequate Shock/Stimulation							
		A090801	Signal Artifact/Noise							
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A1301	Failure to Read Input Signal					
				A0709	Device Sensing Problem					
				A070909	Oversensing					
				A071302	Inappropriate/Inadequate Shock/Stimulation					
				A090801	Signal Artifact/Noise					
	F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal						
			A0709	Device Sensing Problem						
			A070909	Oversensing						
			A071302	Inappropriate/Inadequate Shock/Stimulation						
			A090801	Signal Artifact/Noise						
	F11	Non-Serious Injury/ Illness/ Impairment	A1301	Failure to Read Input Signal						
			A0709	Device Sensing Problem						
			A070909	Oversensing						
			A071302	Inappropriate/Inadequate Shock/Stimulation						
A090801			Signal Artifact/Noise							
F2203	Imaging Required	A1301	Failure to Read Input Signal							
		A0709	Device Sensing Problem							
		A070909	Oversensing							
		A071302	Inappropriate/Inadequate Shock/Stimulation							
		A090801	Signal Artifact/Noise							
CT3006	Implantable inorganic material	E2104	Electric Shock	A1301	Failure to Read Input Signal					
				A0709	Device Sensing Problem					
				A070909	Oversensing					
				A071302	Inappropriate/Inadequate Shock/Stimulation					
				A090801	Signal Artifact/Noise					
	F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal						
			A0709	Device Sensing Problem						
			A070909	Oversensing						
			A071302	Inappropriate/Inadequate Shock/Stimulation						
			A090801	Signal Artifact/Noise						
	F11	Non-Serious Injury/ Illness/ Impairment	A1301	Failure to Read Input Signal						
			A0709	Device Sensing Problem						
			A070909	Oversensing						
			A071302	Inappropriate/Inadequate Shock/Stimulation						
A090801			Signal Artifact/Noise							
F2203	Imaging Required	A1301	Failure to Read Input Signal							
		A0709	Device Sensing Problem							
		A070909	Oversensing							
		A071302	Inappropriate/Inadequate Shock/Stimulation							
		A090801	Signal Artifact/Noise							
CT3007	Implantable ceramic	E2104	Electric Shock	A1301	Failure to Read Input Signal					
				A0709	Device Sensing Problem					
				A070909	Oversensing					
				A071302	Inappropriate/Inadequate Shock/Stimulation					
				A090801	Signal Artifact/Noise					
	F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal						
			A0709	Device Sensing Problem						
			A070909	Oversensing						
			A071302	Inappropriate/Inadequate Shock/Stimulation						
			A090801	Signal Artifact/Noise						
	F11	Non-Serious Injury/ Illness/ Impairment	A1301	Failure to Read Input Signal						
			A0709	Device Sensing Problem						
			A070909	Oversensing						
			A071302	Inappropriate/Inadequate Shock/Stimulation						
A090801			Signal Artifact/Noise							
F2203	Imaging Required	A1301	Failure to Read Input Signal							
		A0709	Device Sensing Problem							
		A070909	Oversensing							
		A071302	Inappropriate/Inadequate Shock/Stimulation							
		A090801	Signal Artifact/Noise							

CT314	Electrically powered	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F11	Non-Serious Injury/ Illness/ Impairment	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT981	Single use	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
		F11	Non-Serious Injury/ Illness/ Impairment	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT983	Surgical invasive	E2104	Electric Shock	A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A0709	Device Sensing Problem		
				A070909	Oversensing		

									A090801	Signal Artifact/Noise		
						F11	Non-Serious Injury/ Illness/ Impairment		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F2203	Imaging Required		A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
5733	2004		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1903	Device Explanation	A1301	Failure to Read Input Signal		
									A0406	Material Deformation		
					CT1150	Defibrillators	F1903	Device Explanation	A0406	Material Deformation		
					CT258	Implantable defibrillators	F1903	Device Explanation	A0406	Material Deformation		
					CT263	Cardiographs and associated devices	F1903	Device Explanation	A0406	Material Deformation		
					CT2866	Implantable cardiac electrical stimulators	F1903	Device Explanation	A0406	Material Deformation		
5734	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		

					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Premature Discharge of Battery		
									A070504	Incorrect, Inadequate or Imprecise Result or Readings		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5735	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
5736	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5737	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2023	12/04/2023
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2023	12/04/2023	
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
						F1903	Device Explanation	A0705	Battery Problem	12/04/2023	12/04/2023	
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2023	12/04/2023
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2023	12/04/2023	
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
						F1903	Device Explanation	A0705	Battery Problem	12/04/2023	12/04/2023	
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2023	12/04/2023
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	12/04/2023	12/04/2023	
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
						F1903	Device Explanation	A0705	Battery Problem	12/04/2023	12/04/2023	
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	12/04/2023	12/04/2023
									A070504	Premature Discharge of Battery	12/04/2023	12/04/2023

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					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
5740	2023		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/03/2023	
							F1901	Additional Surgery	A070909	Oversensing	01/03/2023	31/03/2023
5741	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5742	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1705	Burning Sensation	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A12	Connection Problem		
						E2104	Electric Shock		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

					A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required		A12	Connection Problem		
					A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
CT1147	Defibrillators and associated devices	E1705	Burning Sensation		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F2203	Imaging Required		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
CT1150	Defibrillators	E1705	Burning Sensation		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F2203	Imaging Required		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
CT141	Electrodes/Leads and associated devices	E1705	Burning Sensation		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F2203	Imaging Required		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
CT145	Cardiovascular devices	E1705	Burning Sensation		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F2203	Imaging Required		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
CT233	Surgical	E1705	Burning Sensation		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		E2104	Electric Shock		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
		F2203	Imaging Required		A0709	Device Sensing Problem		
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		

CT2406	Implantable	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT2407	Active implantable	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT258	Implantable defibrillators	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT263	Cardiographs and associated devices	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT2726	Physiological monitoring/measuring devices	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT2727	Active implant devices/ancillaries	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A12	Connection Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
				A0709	Device Sensing Problem		

			Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT2806	Implantable cardiac electrical stimulators	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT2985	Active	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT3001	Implantable metal	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT3002	Implantable synthetic polymer	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
		F2203	Imaging Required	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A12	Connection Problem		
CT3006	Implantable inorganic material	E1705	Burning Sensation	A0709	Device Sensing Problem		
				A070909	Oversensing		

					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT3007	Implantable ceramic	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT314	Electrically powered	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT321	Long-term surgical invasive	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT449	Generators and associated devices	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F2203	Imaging Required	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				CT981	Single use	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				E2104	Electric Shock	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A12	Connection Problem		
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
					A070909	Oversensing		
					A071302	Inappropriate/Inadequate Shock/Stimulation		

								F2203	Imaging Required	A12 A0709 A070909 A071302 A12	Connection Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Connection Problem			
					CT983	Surgical invasive	E1705	Burning Sensation	A0709 A070909 A071302 A12	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Connection Problem				
							E2104	Electric Shock	A0709 A070909 A071302 A12	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Connection Problem				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A12	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Connection Problem				
							F2203	Imaging Required	A0709 A070909 A071302 A12	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Connection Problem				
5743	2023		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A160602 A160602	Premature End-of-Life Indicator Premature End-of-Life Indicator				
5744	2023		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1147	Defibrillators and associated devices	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1150	Defibrillators	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1141	Electrodes/Leads and associated devices	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1145	Cardiovascular devices	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1233	Surgical	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT12406	Implantable	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT12407	Active implantable	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1258	Implantable defibrillators	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1263	Cardiographs and associated devices	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT12726	Physiological monitoring/measuring devices	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT12727	Active implant devices/ancillaries	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT12750	Implantable cardiac electrical stimulators and associated devices	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT12866	Implantable cardiac electrical stimulators	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT12985	Active	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT13001	Implantable metal	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT13002	Implantable synthetic polymer	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT13006	Implantable inorganic material	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT13007	Implantable ceramic	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1314	Electrically powered	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1321	Long-term surgical invasive	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1449	Generators and associated devices	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1981	Single use	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
					CT1983	Surgical invasive	E0601 F12	Arrhythmia Serious Injury/ Illness/ Impairment	A071201 A071201	Failure to Convert Rhythm Failure to Convert Rhythm				
5745	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2336	Shock	A070909 A0712 A071302 A090801	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A071302 A090801	Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise				
5746	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	28/02/2023 28/02/2023 28/02/2023		28/02/2023	
					CT1147	Defibrillators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	28/02/2023 28/02/2023 28/02/2023		28/02/2023	
					CT1150	Defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	28/02/2023 28/02/2023 28/02/2023		28/02/2023	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/02/2023		28/02/2023	

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					CT2866	Implantable cardiac electrical stimulators and associated devices	P1905 E2403 F08 F12 P1905	Device Revision or Replacement No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Serious Injury/ Illness/ Impairment Device Revision or Replacement	A070504 A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	17/05/2023 17/05/2023 17/05/2023 17/05/2023 17/05/2023	17/05/2023 17/05/2023 17/05/2023 17/05/2023 17/05/2023
5749	2023	Death	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT1150	Defibrillators	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT141	Electrodes/Leads and associated devices	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT145	Cardiovascular devices	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT233	Surgical	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT2406	Implantable	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT2407	Active implantable	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT258	Implantable defibrillators	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT2727	Active implant devices/ancillaries	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT2866	Implantable cardiac electrical stimulators	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT2985	Active	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT3001	Implantable metal	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT3002	Implantable synthetic polymer	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT3006	Implantable inorganic material	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT3007	Implantable ceramic	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT314	Electrically powered	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT321	Long-term surgical invasive	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT449	Generators and associated devices	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT981	Single use	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
					CT983	Surgical invasive	E0611 F02	Heart Failure/Congestive Heart Failure Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
5750	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A072201 A072201	High Impedance High Impedance		
5751	2023		37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT1150	Defibrillators	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT141	Electrodes/Leads and associated devices	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT145	Cardiovascular devices	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT233	Surgical	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT2406	Implantable	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT2407	Active implantable	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT258	Implantable defibrillators	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT2727	Active implant devices/ancillaries	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT2866	Implantable cardiac electrical stimulators	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT2985	Active	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT3001	Implantable metal	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT3002	Implantable synthetic polymer	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT3006	Implantable inorganic material	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT3007	Implantable ceramic	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT314	Electrically powered	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT321	Long-term surgical invasive	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT449	Generators and associated devices	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		
					CT981	Single use	F26 F27	No Health Consequences or Impact Problem Identified During Non-Clinical Procedure	A09 A09	Output Problem Output Problem		

					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT0981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT0983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery			
5755	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					F1905		Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	
					CT0981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
					F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023	

					CT983	Surgical invasive	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2023	30/05/2023
8756	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/04/2023	20/04/2023
									A070504	Premature Discharge of Battery	20/04/2023	20/04/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/04/2023	20/04/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/04/2023	20/04/2023

				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT12727	Active implant devices/incineraries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT13007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
		F1905	Device Revision or Replacement	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023
CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	2004/2023	2004/2023
				A070504	Premature Discharge of Battery	2004/2023	2004/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	2004/2023	2004/2023

					CT141	Electrodes/Leads and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT145	Cardiovascular devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT233	Surgical	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2406	Implantable	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2407	Active implantable	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT258	Implantable defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2727	Active implant devices/ancillaries	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT2985	Active	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT3001	Implantable metal	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT3002	Implantable synthetic polymer	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT3006	Implantable inorganic material	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT3007	Implantable ceramic	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT314	Electrically powered	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT321	Long-term surgical invasive	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT449	Generators and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT981	Single use	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
					CT983	Surgical invasive	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
5763	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	31/05/2023 31/05/2023 31/05/2023	31/05/2023 31/05/2023 31/05/2023
					CT1150	Defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	31/05/2023 31/05/2023 31/05/2023	31/05/2023 31/05/2023 31/05/2023
					CT258	Implantable defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	31/05/2023 31/05/2023 31/05/2023	31/05/2023 31/05/2023 31/05/2023
					CT263	Cardiographs and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	31/05/2023 31/05/2023 31/05/2023	31/05/2023 31/05/2023 31/05/2023
					CT2866	Implantable cardiac electrical stimulators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	31/05/2023 31/05/2023 31/05/2023	31/05/2023 31/05/2023 31/05/2023
5764	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403 F24	No Clinical Signs, Symptoms or Conditions Insufficient Health Impact Information	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT1150	Defibrillators	E2403 F24	No Clinical Signs, Symptoms or Conditions Insufficient Health Impact Information	A070504 A0705	Premature Discharge of Battery Battery Problem		
					CT141	Electrodes/Leads and associated devices	E2403 F24	No Clinical Signs, Symptoms or Conditions Insufficient Health Impact Information	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403 F24	No Clinical Signs, Symptoms or Conditions Insufficient Health Impact Information	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT233	Surgical	E2403 F24	No Clinical Signs, Symptoms or Conditions Insufficient Health Impact Information	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5786	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact		A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		

						associated devices			A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5767	2023		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070910	Undersensing	05/06/2023	05/06/2023
							F02	Death	A070910	Undersensing	05/06/2023	05/06/2023
5768	2023		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0112	Dizziness	A070909	Oversensing	01/06/2023	01/06/2023
									A071204	No Pacing	01/06/2023	01/06/2023
							F1901	Additional Surgery	A070909	Oversensing	01/06/2023	01/06/2023
									A071204	No Pacing	01/06/2023	01/06/2023
5769	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A1601	Device Alarm System		

						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System		
								F26	No Health Consequences or Impact	A1601	Device Alarm System		
5770	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
5771	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
								F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
5772	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A072201	High Impedance			
									A072201	High Impedance			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
						CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
						CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
						CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
						CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
						CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
						CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
								F10	Inadequate/Inappropriate Treatment or Diagnostic	A070909	Oversensing		

			Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT314	Electrically powered	F26	No Health Consequences or Impact	A070909	Oversensing		
							E210401	Shock from Patient Lead(s)	A070909	Oversensing		
					CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E210401	Shock from Patient Lead(s)	A070909	Oversensing		
					CT449	Generators and associated devices	F26	No Health Consequences or Impact	A070909	Oversensing		
							E210401	Shock from Patient Lead(s)	A070909	Oversensing		
					CT981	Single use	F26	No Health Consequences or Impact	A070909	Oversensing		
							E210401	Shock from Patient Lead(s)	A070909	Oversensing		
					CT983	Surgical invasive	F26	No Health Consequences or Impact	A070909	Oversensing		
							E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
5776	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5777	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
									A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
									A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
									A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
									A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
									A070504	Premature Discharge of Battery	19/05/2023	19/05/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/05/2023	19/05/2023
5778	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/10/2023	10/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/10/2023	10/10/2023
									A0705	Battery Problem	10/10/2023	10/10/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/10/2023	10/10/2023
									A070504	Premature Discharge of Battery	10/10/2023	10/10/2023
5779	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A090801	Signal Artifact/Noise		

						CT2406	Implantable	F26	No Health Consequences or Impact	A070909	Oversensing		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT149	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
5781	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/10/2023	03/10/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/10/2023	03/10/2023		
5782	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023			
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	31/08/2023	31/08/2023		

							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023
							F1905	Device Revision or Replacement	A070504	Incorrect, Inadequate or Improper Result or Readings	31/08/2023	31/08/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/08/2023	31/08/2023
							F1905	Device Revision or Replacement	A070504	Incorrect, Inadequate or Improper Result or Readings	31/08/2023	31/08/2023
5783	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	20/06/2023	20/06/2023
5784	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2023	23/01/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/01/2023	23/01/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/01/2023	23/01/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/01/2023	23/01/2023
5785	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	23/06/2023	23/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
						CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	23/06/2023	23/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
						CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	23/06/2023	23/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
						CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	23/06/2023	23/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
						CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	23/06/2023	23/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
						CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	23/06/2023	23/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023</

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023
5786	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5787	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F2203	Imaging Required	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2406	Implantable	E2104	Electric Shock	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F2203	Imaging Required	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2407	Active implantable	E2104	Electric Shock	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F2203	Imaging Required	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F2203	Imaging Required	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F2203	Imaging Required	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F2203	Imaging Required	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F2203	Imaging Required	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
		F2203	Imaging Required	A070909	Overensing		

				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F2203	Imaging Required	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive	E2104	Electric Shock	A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
5788	2023	All other reportable incidents				CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
5789	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
							F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016

						CT3007	Implantable ceramic	F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
								E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
								F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
								F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
								F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
								F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
								F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem	21/04/2016	21/04/2016
								F1908	Prolonged Surgery	A12	Connection Problem	21/04/2016	21/04/2016
5790	2023	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/09/2023	26/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2023	26/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/09/2023	26/09/2023	
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2023	26/09/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	26/09/2023	26/09/2023	
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2023	26/09/2023
5791	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/07/2023	25/07/2023	
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/07/2023	25/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/07/2023	25/07/2023	
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/07/2023	25/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	25/07/2023	25/07/2023	
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/07/2023	25/07/2023
5792	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT233	Surgical	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2407	Active implantable	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
5793	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2023	03/02/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2023	03/02/2023
									A070504	Premature Discharge of Battery	03/02/2023	03/02/2023

				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
		F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
		F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
CT1141	Electrodes/leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
		F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
		F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
		F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
		F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
		F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
		F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023

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CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
	F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
			A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
	F1905	Device Revision or Replacement	A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
			A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
	F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
	F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
CT1314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
	F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
CT1321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
	F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
	F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
	F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
	F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023	
			A0508	Noise, Audible	27/06/2023	27/06/2023	
			A0705	Battery Problem	27/06/2023	27/06/2023	
			A070504	Premature Discharge of Battery	27/06/2023	27/06/2023	
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				A0508	Noise, Audible	27/06/2023	27/06/2023
				A0705	Battery Problem	27/06/2023	27/06/2023
				A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
				A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
				F08	Noise, Audible	27/06/2023	27/06/2023

										A0705	Battery Problem	27/06/2023	27/06/2023
										A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
										A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
						F1905	Device Revision or Replacement			A0508	Noise, Audible	27/06/2023	27/06/2023
										A0705	Battery Problem	27/06/2023	27/06/2023
										A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
										A1304	Telemetry Discrepancy	27/06/2023	27/06/2023
5795	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
5796	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
5797	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023	
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023	
5798	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal			
									A1301	Pacing Problem			
									A1301	Failure to Read Input Signal			
5799	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
					CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
									A071301	Failure to Deliver Shock/Stimulation			

CT141	Electrodes/Leads and associated devices	F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
		F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation			
				A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT145	Cardiovascular devices	F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT233	Surgical	E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT2406	Implantable	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT2407	Active implantable	F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT258	Implantable defibrillators	F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT2750	Implantable cardiac electrical stimulators and associated devices	F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT2866	Implantable cardiac electrical stimulators	F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT2985	Active	F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F23	Unexpected Medical Intervention	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
CT3001	Implantable metal	E060109	Tachycardia	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem			
				A071301	Failure to Deliver Shock/Stimulation			
		F1203	Life Threatening illness or injury	A0709	Device Sensing Problem			

					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5601	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		

					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery		
									A070504	Battery Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A0705	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery		
									A070504	Battery Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5802	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery		
									A070504	Battery Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Battery Problem		
									A0705	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Premature Discharge of Battery		
									A070504	Battery Problem		
5803	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Overensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Overensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Overensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909	Overensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
					CT233	Surgical	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

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							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
					CT141	Electrodes/Leads and associated devices	F23	Unexpected Medical Intervention	A0712	Pacing Problem		
							E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
					CT145	Cardiovascular devices	F23	Unexpected Medical Intervention	A0712	Pacing Problem		
							E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT233	Surgical	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT2406	Implantable	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT2407	Active implantable	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT2727	Active implant devices/ancillaries	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT2985	Active	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT3001	Implantable metal	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT3002	Implantable synthetic polymer	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT3007	Implantable ceramic	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT314	Electrically powered	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT449	Generators and associated devices	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT981	Single use	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT983	Surgical invasive	E060109	Tachycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
5806	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A0709 A070909 A070910 A071302	Device Sensing Problem Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A0709 A070909 A070910 A071302	Device Sensing Problem Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
5807	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04 A070909 A090801	Material Integrity Problem Oversensing Signal Artifact/Noise	06/03/2023 06/03/2023 06/03/2023	06/03/2023 06/03/2023 06/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A04 A070909 A090801	Material Integrity Problem Oversensing Signal Artifact/Noise	06/03/2023 06/03/2023 06/03/2023	06/03/2023 06/03/2023 06/03/2023
							F1905	Device Revision or Replacement	A04 A070909 A090801	Material Integrity Problem Oversensing Signal Artifact/Noise	06/03/2023 06/03/2023 06/03/2023	06/03/2023 06/03/2023 06/03/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04 A070909 A090801	Material Integrity Problem Oversensing Signal Artifact/Noise	06/03/2023 06/03/2023 06/03/2023	06/03/2023 06/03/2023 06/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A04 A070909 A090801	Material Integrity Problem Oversensing Signal Artifact/Noise	06/03/2023 06/03/2023 06/03/2023	06/03/2023 06/03/2023 06/03/2023
							F1905	Device Revision or Replacement	A04 A070909 A090801	Material Integrity Problem Oversensing Signal Artifact/Noise	06/03/2023 06/03/2023 06/03/2023	06/03/2023 06/03/2023 06/03/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A04 A070909 A090801	Material Integrity Problem Oversensing Signal Artifact/Noise	06/03/2023 06/03/2023 06/03/2023	06/03/2023 06/03/2023 06/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A04	Material Integrity Problem	06/03/2023	06/03/2023

5808	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070909	Oversensing	06/03/2023	06/03/2023
									A090801	Signal Artifact/Noise	06/03/2023	06/03/2023
									A04	Material Integrity Problem	06/03/2023	06/03/2023
									A070909	Oversensing	06/03/2023	06/03/2023
									A090801	Signal Artifact/Noise	06/03/2023	06/03/2023
									A071102	Failure to Interrogate		
							F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
		F1901	Additional Surgery	A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							
				A071102	Failure to Interrogate							
				A160503	Inappropriate or Unexpected Reset							

					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
							F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
							F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset		
									A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A071102	Failure to Interrogate		
									A160503	Inappropriate or Unexpected Reset		
5809	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
									A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/07/2023	04/07/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	04/07/2023	04/07/2023

					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F23	Unexpected Medical Intervention	A0713	Defibrillation/Stimulation Problem		
5812	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
5813	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A0709 A070909 A071302	Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
5814	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings		
							F23	No Health Consequences or Impact	A090811	Unable to Obtain Readings		
5815	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
5816	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	implantable defibrillators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	implantable synthetic polymer	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	implantable inorganic material	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	Implantable ceramic	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		

5817	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT12726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT12727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT12750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT12985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT13001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT13002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
					CT13006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	11/05/2022	11/05/2022

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	24/06/2022	24/06/2022
5820	2022	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
					F1901	Additional Surgery	A070504		A070504	Premature Discharge of Battery	26/10/2022	26/10/2022
5821	2022	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
									A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
									A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
									A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
									A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
									A070908	Failure to Sense	08/11/2022	08/11/2022
									A072201	High Impedance	08/11/2022	08/11/2022

		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
		F1901	Additional Surgery	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022
				A072201	High Impedance	08/11/2022	08/11/2022
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture	08/11/2022	08/11/2022
				A070908	Failure to Sense	08/11/2022	08/11/2022

							F1901	Additional Surgery	A072201 A070101 A070908 A072201	High Impedance Failure to Capture Failure to Sense High Impedance	08/11/2022 08/11/2022 08/11/2022 08/11/2022	08/11/2022 08/11/2022 08/11/2022 08/11/2022
5822	2023		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401 F02	Insufficient Information Death	A24 A24	No Apparent Device Problem No Apparent Device Problem		
5823	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A0705 A070504 A0908 A0705 A070504 A0908 A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023	27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023 27/11/2023
5824	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F1903	No Clinical Signs, Symptoms or Conditions Device Explanation	A180601 A180601	Premature Elective Replacement Indicator Premature Elective Replacement Indicator	04/08/2023 04/08/2023	04/08/2023 04/08/2023
5825	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403 F26	No Clinical Signs, Symptoms or Conditions No Health Consequences or Impact	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery		
5826	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT1147	Defibrillators and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT1150	Defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT141	Electrodes/Leads and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT145	Cardiovascular devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT233	Surgical	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT2406	Implantable	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT2407	Active implantable	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT258	Implantable defibrillators	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT263	Cardiographs and associated devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT2726	Physiological monitoring/measuring devices	E2403 F08 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Revision or Replacement	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023
					CT2727	Active implant devices/ancillaries	E2403 F08	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/03/2023 28/03/2023 28/03/2023 28/03/2023	28/03/2023 28/03/2023 28/03/2023 28/03/2023

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		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		

									A1301	Failure to Read Input Signal		
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A090801	Signal Artifact/Noise			
								A1301	Failure to Read Input Signal			
				CT1449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A090801	Signal Artifact/Noise			
								A1301	Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A090801	Signal Artifact/Noise			
				CT0981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A090801	Signal Artifact/Noise			
								A1301	Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A090801	Signal Artifact/Noise			
				CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A090801	Signal Artifact/Noise			
								A1301	Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A070909	Oversensing			
								A090801	Signal Artifact/Noise			
5828	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing	
5829	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/05/2023	04/05/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/05/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/05/2023
5830	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
				CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
				CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
				CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
				CT1145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
				CT1233	Surgical	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

CT2406	Implantable	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT2985	Active	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909 A071302 A090801	Signal Artifact/Noise Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT314	Electrically powered	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT449	Generators and associated devices	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT981	Single use	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
					CT983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			
5831	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
5832	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023		04/04/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023		04/04/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023		04/04/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023		04/04/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/04/2023		04/04/2023
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	04/04/2023		04/04/2023
5833	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023		22/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/09/2023		22/09/2023
									A070504	Premature Discharge of Battery	22/09/2023		22/09/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/09/2023		22/09/2023
									A070504	Premature Discharge of Battery	22/09/2023		22/09/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/09/2023		22/09/2023
									A070504	Premature Discharge of Battery	22/09/2023		22/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/09/2023		22/09/2023

CT1150	Defibrillators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0909		A0909	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT141	Electrodes/Leads and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0909		A0909	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0909		A0909	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT2407	Active implantable	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0909		A0909	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0909		A0909	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT2727	Active implant devices/ancillaries	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0909		A0909	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0909		A0909	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT3001	Implantable metal	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0909		A0909	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/09/2023	22/09/2023
		A0908		A0908	Incorrect, Inadequate or Improper Result or Readings	22/09/2023	22/09/2023

5837	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improvised Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/09/2023	13/09/2023
									A0908	Incorrect, Inadequate or Improvised Result or Readings	13/09/2023	13/09/2023
									A070504	Premature Discharge of Battery	13/09/2023	13/09/2023
F1903	Device Explantation	A0908	Incorrect, Inadequate or Improvised Result or Readings	13/09/2023	13/09/2023							
5838	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
									A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
									A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
									A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
									A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
									A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
									A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023							
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
									A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
									A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
									A070504	Premature Discharge of Battery	26/10/2023	26/10/2023
									A0908	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/10/2023	26/10/2023							
5839	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A24	Incorrect, Inadequate or Improvised Result or Readings	26/10/2023	26/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT1147	Defibrillators and associated devices	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT1150	Defibrillators	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT1141	Electrodes/Leads and associated devices	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT1145	Cardiovascular devices	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT1233	Surgical	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT12406	Implantable	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT12407	Active implantable	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT2726	Physiological monitoring/measuring devices	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT2727	Active implant devices/ancillaries	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT2750	Implantable cardiac electrical stimulators and associated devices	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT2985	Active	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT3001	Implantable metal	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT3002	Implantable synthetic polymer	E1906	Unspecified Infection	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
									A24	No Apparent Device Problem		
									F1905	Device Revision or Replacement	A24	No Apparent Device Problem
					CT3006	Implantable inorganic material	E1906	Unspecified Infection	A24	No Apparent Device Problem		

								F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
								F1905	Device Revision or Replacement	A24	No Apparent Device Problem		
					CT3007	Implantable ceramic		E1906	Unspecified Infection	A24	No Apparent Device Problem		
								F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
								F1905	Device Revision or Replacement	A24	No Apparent Device Problem		
					CT314	Electrically powered		E1906	Unspecified Infection	A24	No Apparent Device Problem		
								F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
								F1905	Device Revision or Replacement	A24	No Apparent Device Problem		
					CT321	Long-term surgical invasive		E1906	Unspecified Infection	A24	No Apparent Device Problem		
								F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
								F1905	Device Revision or Replacement	A24	No Apparent Device Problem		
					CT449	Generators and associated devices		E1906	Unspecified Infection	A24	No Apparent Device Problem		
								F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
								F1905	Device Revision or Replacement	A24	No Apparent Device Problem		
					CT981	Single use		E1906	Unspecified Infection	A24	No Apparent Device Problem		
								F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
								F1905	Device Revision or Replacement	A24	No Apparent Device Problem		
					CT983	Surgical invasive		E1906	Unspecified Infection	A24	No Apparent Device Problem		
								F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
								F1905	Device Revision or Replacement	A24	No Apparent Device Problem		
5840	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	15/08/2023	15/08/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
5841	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/07/2022	15/07/2022
5842	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
					CT145	Cardiovascular devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT141	Electrodes/Leads and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT233	Surgical	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT2407	Active implantable	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT263	Cardiographs and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT449	Generators and associated devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
CT983	Surgical invasive	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A1301	Failure to Read Input Signal		
				A0712	Pacing Problem		

5848	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT1145	Cardiovascular devices	E2104	Electric Shock	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT233	Surgical	E2104	Electric Shock	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT2406	Implantable	E2104	Electric Shock	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909 A090801 A1301	Signal Artifact/Noise	01/12/2022	01/12/2022
					CT2407	Active implantable	E2104	Electric Shock	A070909 A090801 A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Signal Artifact/Noise	01/12/2022	01/12/2022

				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2985	Active	E2104	Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
				A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
				A1301	Failure to Read Input Signal	01/12/2022	01/12/2022

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									A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
									A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
									A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
									A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
									A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
									A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
									A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
									A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
									A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
									A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
									A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F1905	Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
									A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
									A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
							F2203	Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
									A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
									A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
5849	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/11/2023	01/11/2023
									A160601	Premature Elective Replacement Indicator	01/11/2023	01/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/11/2023	01/11/2023
									A160601	Premature Elective Replacement Indicator	01/11/2023	01/11/2023
							F1903	Device Explantation	A070504	Premature Discharge of Battery	01/11/2023	01/11/2023
									A160601	Premature Elective Replacement Indicator	01/11/2023	01/11/2023
5850	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5851	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0701	Capturing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A0701	Capturing Problem		
							F12	Serious Injury/Illness/ Impairment	A0701	Capturing Problem		
							F23	Unexpected Medical Intervention	A0701	Capturing Problem		
5852	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT2406	implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0722	Impedance Problem		
									A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		

						F26	No Health Consequences or Impact	A072201	High Impedance		
						E2403	No Clinical Signs, Symptoms or Conditions	A07221	Impedance Problem		
								A07221	High Impedance		
						F26	No Health Consequences or Impact	A0722	Impedance Problem		
								A072201	High Impedance		
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								A072201	High Impedance		
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								A072201	High Impedance		
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						C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/09/2023	26/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/09/2023	26/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/09/2023	26/09/2023
5858	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
								F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5859	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		C1258	Implantable defibrillators	E0801	Arrhythmia	A071301	Failure to Deliver Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A071301	Failure to Deliver Shock/Stimulation		
5860	2023	All other reportable incidents				C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/09/2023	20/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2023	20/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/09/2023	20/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2023	20/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/09/2023	20/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2023	20/09/2023
5861	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator		C11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/09/2023	11/09/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/09/2023	11/09/2023

					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5667	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
5668	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT233	Surgical	E2104	Electric Shock	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2406	Implantable	E2104	Electric Shock	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2407	Active implantable	E2104	Electric Shock	A070909 A071302 A1301	Overensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		

		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT2985	Active	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT3001	Implantable metal	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT3007	Implantable ceramic	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation		
			CT983	Surgical invasive		E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
5869	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						P1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						P1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						P1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						P1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						P1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
					CT233	Surgical	E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						P1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
					CT2406	Implantable	E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
						P1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022

					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203		Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2407	Active implantable	E2104		Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905		Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203		Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT258	Implantable defibrillators	E2104		Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905		Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203		Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT263	Cardiographs and associated devices	E2104		Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905		Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203		Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2726	Physiological monitoring/measuring devices	E2104		Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905		Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203		Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2727	Active implant devices/ancillaries	E2104		Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905		Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203		Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104		Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905		Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203		Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
CT2866	Implantable cardiac electrical stimulators	E2104		Electric Shock	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F1905		Device Revision or Replacement	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022
		F2203		Imaging Required	A070909	Oversensing	01/12/2022	01/12/2022
					A090801	Signal Artifact/Noise	01/12/2022	01/12/2022
					A1301	Failure to Read Input Signal	01/12/2022	01/12/2022

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								F1905	Device Revision or Replacement	A1301 A070909 A090801 A1301	Failure to Read Input Signal Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022 01/12/2022
								F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
				C1981	Single use			E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
								F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
								F1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
								F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
				C1983	Surgical Invasive			E2104	Electric Shock	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
								F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
								F1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
								F2203	Imaging Required	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	01/12/2022 01/12/2022 01/12/2022	01/12/2022 01/12/2022 01/12/2022
5870	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	31/07/2023 31/07/2023	31/07/2023 31/07/2023	31/07/2023 31/07/2023
					CT258	Implantable defibrillators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	31/07/2023 31/07/2023	31/07/2023 31/07/2023	31/07/2023 31/07/2023
					CT2866	Implantable cardiac electrical stimulators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	31/07/2023 31/07/2023	31/07/2023 31/07/2023	31/07/2023 31/07/2023
5871	2023	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601 F02	Arrhythmia Death	A070910 A070912 A071301 A070910 A070912 A071301	Undersensing Incorrect Interpretation of Signal Failure to Deliver Shock/Stimulation Undersensing Incorrect Interpretation of Signal Failure to Deliver Shock/Stimulation	16/10/2020 16/10/2020 16/10/2020 16/10/2020 16/10/2020 16/10/2020	16/10/2020 16/10/2020 16/10/2020 16/10/2020 16/10/2020 16/10/2020	
5872	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT1150	Defibrillators	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT141	Electrodes/Leads and associated devices	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT145	Cardiovascular devices	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT233	Surgical	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT2406	Implantable	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT2407	Active implantable	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT258	Implantable defibrillators	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT2727	Active implant devices/ancillaries	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT2866	Implantable cardiac electrical stimulators	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT2985	Active	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT3001	Implantable metal	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT3002	Implantable synthetic polymer	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT3006	Implantable inorganic material	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT3007	Implantable ceramic	E0601 F10	Arrhythmia Inadequate/inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem			
					CT314	Electrically powered	E0601	Arrhythmia	A0712	Pacing Problem			

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E0601	Arrhythmia	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT449	Generators and associated devices	E0601	Arrhythmia	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT981	Single use	E0601	Arrhythmia	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT983	Surgical invasive	E0601	Arrhythmia	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
5873	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT1150	Defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT145	Cardiovascular devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT233	Surgical	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT2406	Implantable	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT2407	Active implantable	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT2985	Active	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT3001	Implantable metal	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT3006	Implantable inorganic material	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT3007	Implantable ceramic	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT314	Electrically powered	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT321	Long-term surgical invasive	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT449	Generators and associated devices	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT981	Single use	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
					CT983	Surgical invasive	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
5874	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E011903	Syncope/Fainting	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E0601	Arrhythmia	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E011903	Syncope/Fainting	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		

						A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				E2104	Electric Shock	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				F2203	Imaging Required	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
			CT141	Electrodes/Leads and associated devices	E011903	Syncopal/Fainting	A070910	Undersensing		
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				E0601	Arrhythmia	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				E2104	Electric Shock	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				F2203	Imaging Required	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
			CT145	Cardiovascular devices	E011903	Syncopal/Fainting	A070910	Undersensing		
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			
				E0601	Arrhythmia	A070910	Undersensing			
						A0712	Pacing Problem			
						A071302	Inappropriate/Inadequate Shock/Stimulation			
						A090801	Signal Artifact/Noise			
						A1301	Failure to Read Input Signal			

				A090801	Signal Artifact/Noise				
				A1301	Failure to Read Input Signal				
		E0601	Arrhythmia	A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		E2104	Electric Shock	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F2203	Imaging Required	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
				A1301	Failure to Read Input Signal				
CT2406	Implantable	E011903	Syncope/Fainting	A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
				A1301	Failure to Read Input Signal				
		E0601	Arrhythmia	A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		E2104	Electric Shock	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F2203	Imaging Required	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
CT2407	Active implantable	E011903	Syncope/Fainting	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		E0601	Arrhythmia	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		E2104	Electric Shock	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
		F2203	Imaging Required	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				
				A071302	Inappropriate/Inadequate Shock/Stimulation				
				A090801	Signal Artifact/Noise				
CT258	Implantable defibrillators	E011903	Syncope/Fainting	A1301	Failure to Read Input Signal				
				A070910	Undersensing				
				A0712	Pacing Problem				

					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E0601	Arrhythmia	A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			E2104	Electric Shock	A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
			F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
					A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
					A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
			P2203	Imaging Required	A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E011903	Syncope/Fainting		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		E0601	Arrhythmia		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		E2104	Electric Shock		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		P2203	Imaging Required		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E011903	Syncope/Fainting		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		E0601	Arrhythmia		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		E2104	Electric Shock		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
		P2203	Imaging Required		A070910	Undersensing		
					A0712	Pacing Problem		
					A071302	Inappropriate/Inadequate Shock/Stimulation		
					A090801	Signal Artifact/Noise		
					A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting		A070910	Undersensing		

						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
			E0601	Arrhythmia		A070910	Undersensing		
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
			E2104	Electric Shock		A070910	Undersensing		
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
			F08	Hospitalization or Prolonged Hospitalization		A070910	Undersensing		
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing		
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
			F2203	Imaging Required		A070910	Undersensing		
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
			CT2985	Active	E011903	Syncopal/Fainting	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					E0601	Arrhythmia	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					E2104	Electric Shock	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					F2203	Imaging Required	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
			CT3001	Implantable metal	E011903	Syncopal/Fainting	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					E0601	Arrhythmia	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					E2104	Electric Shock	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		
					F2203	Imaging Required	A070910	Undersensing	
						A0712	Pacing Problem		
						A071302	Inappropriate/Inadequate Shock/Stimulation		
						A090801	Signal Artifact/Noise		
						A1301	Failure to Read Input Signal		

CT3002	Implantable synthetic polymer	E011903	Syncope/Fainting	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E011903	Syncope/Fainting	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E011903	Syncope/Fainting	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		

CT314	Electrically powered	E011903	Syncope/Fainting	A1301	Failure to Read Input Signal		
				A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E011903	Syncope/Fainting	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
CT449	Generators and associated devices	E011903	Syncope/Fainting	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		E0601	Arrhythmia	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		E2104	Electric Shock	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
				A1301	Failure to Read Input Signal		
		F2203	Imaging Required	A070910	Undersensing		
				A0712	Pacing Problem		
				A071302	Inappropriate/Inadequate Shock/Stimulation		

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								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
								A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
						F1903	Device Explanation	A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
								A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
						F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
								A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
								A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
								A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
						F1903	Device Explanation	A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
								A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
						F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
								A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
								A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
								A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
						F1903	Device Explanation	A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
								A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
						F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
								A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
								A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
								A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
						F1903	Device Explanation	A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
								A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
						F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
								A0705	Battery Problem	05/10/2023	05/10/2023
								A070504	Premature Discharge of Battery	05/10/2023	05/10/2023
								A1304	Telemetry Discrepancy	05/10/2023	05/10/2023
5876	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5877	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold	
								A070102	High Capture Threshold		
						F19	Surgical Intervention	A070102	High Capture Threshold		
5878	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/10/2023
								A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
5879	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/09/2023
								A071102	Failure to Interrogate	13/09/2023	13/09/2023
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/09/2023	13/09/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/09/2023
								A071102	Failure to Interrogate	13/09/2023	13/09/2023
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/09/2023	13/09/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	13/09/2023
								A071102	Failure to Interrogate	13/09/2023	13/09/2023
						F1905	Device Revision or Replacement	A071102	Failure to Interrogate	13/09/2023	13/09/2023
5880	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A010402	Migration	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						E2117	Twiddlers Syndrome	A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						F1903	Device Explanation	A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						F2203	Imaging Required	A010402	Migration	14/09/2023	14/09/2023

						A070802	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			P23	Unexpected Medical Intervention		A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			CT1147	Defibrillators and associated devices	E2104	A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						A010402	Migration	14/09/2023	14/09/2023
						A070602	Delayed Charge Time	14/09/2023	14/09/2023
						A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
						A072202	Low Impedance	14/09/2023	14/09/2023
						A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
						A010402	Migration	14/09/2023	14/09/2023

					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F23	Unexpected Medical Intervention	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			E2104	Electric Shock	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			E2117	Tiddlers Syndrome	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F1903	Device Explanation	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F2203	Imaging Required	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F23	Unexpected Medical Intervention	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			E2104	Electric Shock	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			E2117	Tiddlers Syndrome	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F1903	Device Explanation	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F2203	Imaging Required	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F23	Unexpected Medical Intervention	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			E2104	Electric Shock	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			E2117	Tiddlers Syndrome	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
					A072202	Low Impedance	14/09/2023	14/09/2023
					A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	14/09/2023	14/09/2023
					A070602	Delayed Charge Time	14/09/2023	14/09/2023
					A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023

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CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
				A072202	Low Impedance	14/09/2023	14/09/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
				A010402	Migration	14/09/2023	14/09/2023
				A070602	Delayed Charge Time	14/09/2023	14/09/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		E2117	Tiddlers Syndrome	A072202	Low Impedance	14/09/2023	14/09/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
				A010402	Migration	14/09/2023	14/09/2023
				A070602	Delayed Charge Time	14/09/2023	14/09/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
				A072202	Low Impedance	14/09/2023	14/09/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
				A010402	Migration	14/09/2023	14/09/2023
				A070602	Delayed Charge Time	14/09/2023	14/09/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
				A072202	Low Impedance	14/09/2023	14/09/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	14/09/2023	14/09/2023
				A070602	Delayed Charge Time	14/09/2023	14/09/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
				A072202	Low Impedance	14/09/2023	14/09/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
				A010402	Migration	14/09/2023	14/09/2023
		F1903	Device Explanation	A070602	Delayed Charge Time	14/09/2023	14/09/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
				A072202	Low Impedance	14/09/2023	14/09/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
				A010402	Migration	14/09/2023	14/09/2023
				A070602	Delayed Charge Time	14/09/2023	14/09/2023
		F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
				A072202	Low Impedance	14/09/2023	14/09/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
				A010402	Migration	14/09/2023	14/09/2023
				A070602	Delayed Charge Time	14/09/2023	14/09/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		F23	Unexpected Medical Intervention	A072202	Low Impedance	14/09/2023	14/09/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
				A010402	Migration	14/09/2023	14/09/2023
				A070602	Delayed Charge Time	14/09/2023	14/09/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
				A072202	Low Impedance	14/09/2023	14/09/2023
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023

							Exposure	A070802	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F1903	Device Explanation		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F2203	Imaging Required		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F23	Unexpected Medical Intervention		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			CT2985	Active	E2104	Electric Shock		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					E2117	Tiddlers Syndrome		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F08	Hospitalization or Prolonged Hospitalization		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F1903	Device Explanation		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F2203	Imaging Required		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F23	Unexpected Medical Intervention		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
			CT3001	Implantable metal	E2104	Electric Shock		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					E2117	Tiddlers Syndrome		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F08	Hospitalization or Prolonged Hospitalization		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F1903	Device Explanation		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F2203	Imaging Required		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
					F23	Unexpected Medical Intervention		A010402	Migration	14/09/2023	14/09/2023
								A070602	Delayed Charge Time	14/09/2023	14/09/2023
								A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
								A072202	Low Impedance	14/09/2023	14/09/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023

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		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
E2117	Twiddlers Syndrome	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F1903	Device Explanation	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F2203	Imaging Required	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F23	Unexpected Medical Intervention	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
E2104	Electric Shock	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
E2117	Twiddlers Syndrome	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F1903	Device Explanation	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F2203	Imaging Required	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F23	Unexpected Medical Intervention	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
E2104	Electric Shock	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
E2117	Twiddlers Syndrome	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023
		A071302	Inappropriate/Inadequate Shock/Stimulation	14/09/2023	14/09/2023
		A072202	Low Impedance	14/09/2023	14/09/2023
		A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/09/2023	14/09/2023
F1903	Device Explanation	A010402	Migration	14/09/2023	14/09/2023
		A070602	Delayed Charge Time	14/09/2023	14/09/2023

								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
						CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
						CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
						CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
						CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
						CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
						CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
						CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	14/06/2023	14/06/2023
5884	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5885	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0623	Unspecified Heart Problem	A070909	Oversensing			
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
5886	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture	16/06/2023	16/06/2023	
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	16/06/2023	16/06/2023
								F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	16/06/2023	16/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A040101	Fracture	16/06/2023	16/06/2023
									A070909	Oversensing	16/06/2023	16/06/2023	
									A090801	Signal Artifact/Noise	16/06/2023	16/06/2023	
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A040101	Fracture	16/06/2023	16/06/2023
									A070909	Oversensing	16/06/2023	16/06/2023	
									A090801	Signal Artifact/Noise	16/06/2023	16/06/2023	
								F1905	Device Revision or Replacement	A040101	Fracture	16/06/2023	16/06/2023
									A070909	Oversensing	16/06/2023	16/06/2023	
									A090801	Signal Artifact/Noise	16/06/2023	16/06/2023	
								F2203	Imaging Required	A040101	Fracture	16/06/2023	16/06/2023
									A070909	Oversensing	16/06/2023	16/06/2023	
									A090801	Signal Artifact/Noise	16/06/2023	16/06/2023	
5887	2023	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
								F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
5888	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem			
									A070504	Premature Discharge of Battery			
5889	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem			
								F26	No Health Consequences or Impact	A072201	High Impedance		
									A0722	Impedance Problem			
									A072201	High Impedance			

CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
		F26	No Health Consequences or Impact	A072201	High Impedance		
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		

5890	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A072201	High Impedance		
									A0722	Impedance Problem		
									A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/06/2023	30/06/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/06/2023	30/06/2023

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[illegible]

CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1903	Device Explanation	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
				A070504	Premature Discharge of Battery	07/12/2023	07/12/2023
		F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/12/2023	07/12/2023
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/12/2023	07/12/2023

5894	2023		37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E21	Procedural Complications	A16	Protective Measures Problem		
					CT1150	Defibrillators	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT1141	Electrodes/Leads and associated devices	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT145	Cardiovascular devices	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT233	Surgical	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT2406	Implantable	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT2407	Active implantable	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT258	Implantable defibrillators	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT2727	Active implant devices/ancillaries	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT2866	Implantable cardiac electrical stimulators	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT2985	Active	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT3001	Implantable metal	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT3002	Implantable synthetic polymer	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT3006	Implantable inorganic material	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT3007	Implantable ceramic	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT314	Electrically powered	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT321	Long-term surgical invasive	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT449	Generators and associated devices	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT981	Single use	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
					CT983	Surgical invasive	E22	Investigations and Diagnostic Tests	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
							E21	Procedural Complications	A16	Protective Measures Problem		
5895	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
5896	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060101	Asystole	A070504	Premature Discharge of Battery		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
							E2007	Fail	A0712	Pacing Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E060101	Asystole	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
							E2007	Fail	A0712	Pacing Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A072201	High Impedance		

CT1150	Defibrillators	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
E2007	Fall	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT141	Electrodes/Leads and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT145	Cardiovascular devices	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT233	Surgical	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2406	Implantable	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
		E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		
CT2407	Active implantable	E060101	Asystole	A070909	Oversensing		
				A0712	Pacing Problem		
				A072201	High Impedance		
				A090801	Signal Artifact/Noise		

					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			E2007	Fail	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
CT258	Implantable defibrillators	E060101	Asystole		A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			E2007	Fail	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E060101	Asystole		A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			E2007	Fail	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
CT2726	Physiological monitoring/measuring devices	E060101	Asystole		A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			E2007	Fail	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E060101	Asystole		A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			E2007	Fail	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E060101	Asystole		A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			E2007	Fail	A070909	Oversensing		
					A0712	Pacing Problem		
					A072201	High Impedance		
					A090801	Signal Artifact/Noise		
			F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
					A0712	Pacing Problem		

				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
				A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
CT2866	Implantable cardiac electrical stimulators	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		E2007	Fall	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
CT2985	Active	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		E2007	Fall	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
CT3001	Implantable metal	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		E2007	Fall	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
CT3002	Implantable synthetic polymer	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		E2007	Fall	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
CT3006	Implantable inorganic material	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		E2007	Fall	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			
				A090801	Signal Artifact/Noise			
CT3007	Implantable ceramic	E060101	Asystole	A070909	Overensing			
				A0712	Pacing Problem			
				A072201	High Impedance			

					A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
C1314	Electrically powered	E060101		Asystole	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
		E2007		Fall	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
		F08		Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
C1321	Long-term surgical invasive	E060101		Asystole	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		E2007		Fall	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
CT449	Generators and associated devices	E060101		Asystole	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
		E2007		Fall	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
		F08		Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
CT981	Single use	E060101		Asystole	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
		E2007		Fall	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
		F08		Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
CT983	Surgical invasive	E060101		Asystole	A090801	Signal Artifact/Noise			
					A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		E2007		Fall	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			
		F08		Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
					A0712	Pacing Problem			
					A072201	High Impedance			
					A090801	Signal Artifact/Noise			

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					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5899	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0119	Loss of Consciousness	A070909	Oversensing		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
									A0909	Unexpected Therapeutic Results		
						E011903	Syncope/Fainting		A070909	Oversensing		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
									A0909	Unexpected Therapeutic Results		
						E2104	Electric Shock		A070909	Oversensing		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
									A0909	Unexpected Therapeutic Results		
						F05	Delay to Treatment/ Therapy		A070909	Oversensing		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
									A0909	Unexpected Therapeutic Results		
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
									A0909	Unexpected Therapeutic Results		
						F1905	Device Revision or Replacement		A070909	Oversensing		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
									A0909	Unexpected Therapeutic Results		
5900	2023		37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT2966	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator	22/09/2023	
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	22/09/2023	

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						F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing	
					CT145	Cardiovascular devices	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT233	Surgical	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT2406	Implantable	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT2407	Active implantable	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT258	Implantable defibrillators	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT2806	Implantable cardiac electrical stimulators	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT2985	Active	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT3001	Implantable metal	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT3002	Implantable synthetic polymer	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT3006	Implantable inorganic material	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT3007	Implantable ceramic	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT314	Electrically powered	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT321	Long-term surgical invasive	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT449	Generators and associated devices	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT981	Single use	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
					CT993	Surgical invasive	E2311	Discomfort	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
9908	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation	
								A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	
								A070909	Oversensing		
								A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
							F1901	Additional Surgery	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909	Oversensing	
								A090801	Signal Artifact/Noise		
							F2301	Additional Device Required	A070909	Oversensing	

5909	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5910	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
5911	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	15/08/2023	15/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A0705	Battery Problem	15/08/2023	15/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	15/08/2023	15/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/08/2023	15/08/2023
5912	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		

					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5913	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5914	2023	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
5915	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
						F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem			
									A070909	Oversensing		

				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
CT145	Cardiovascular devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A23	Use of Device Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F25	Unanticipated Adverse Device Effect	A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F25	Unanticipated Adverse Device Effect	A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F25	Unanticipated Adverse Device Effect	A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F25	Unanticipated Adverse Device Effect	A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F25	Unanticipated Adverse Device Effect	A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/inadequate Shock/Stimulation		
		F25	Unanticipated Adverse Device Effect	A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		

				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F25	Unanticipated Adverse Device Effect	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
CT3001	Implantable metal	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		
				A0709	Device Sensing Problem		
				A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
				A1301	Failure to Read Input Signal		
				A23	Use of Device Problem		

		P25	Unanticipated Adverse Device Effect	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		P25	Unanticipated Adverse Device Effect	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
CT3006	Implantable inorganic material	E2104	Electric Shock	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		P25	Unanticipated Adverse Device Effect	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
CT3007	Implantable ceramic	E2104	Electric Shock	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		P25	Unanticipated Adverse Device Effect	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
CT314	Electrically powered	E2104	Electric Shock	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		P25	Unanticipated Adverse Device Effect	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
CT321	Long-term surgical invasive	E2104	Electric Shock	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		P25	Unanticipated Adverse Device Effect	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
CT449	Generators and associated devices	E2104	Electric Shock	A0709 A070909 A071302 A1301 A23	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Use of Device Problem				
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal				

							F25	Unanticipated Adverse Device Effect	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
				CT981	Single use	E2104	Electric Shock	A0709 A070909 A071302 A1301	A23 Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal	Use of Device Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301	A23 Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal	Use of Device Problem		
						F25	Unanticipated Adverse Device Effect	A0709 A070909 A071302 A1301	A23 Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal	Use of Device Problem		
				CT983	Surgical invasive	E2104	Electric Shock	A0709 A070909 A071302 A1301	A23 Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal	Use of Device Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301	A23 Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal	Use of Device Problem		
						F25	Unanticipated Adverse Device Effect	A0709 A070909 A071302 A1301	A23 Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal	Use of Device Problem		
5916	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909	Device Sensing Problem Oversensing			

CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT2985	Active	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT3001	Implantable metal	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT3002	Implantable synthetic polymer	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT3006	Implantable inorganic material	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT3007	Implantable ceramic	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT314	Electrically powered	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT321	Long-term surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT449	Generators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		
CT983	Surgical invasive	E2104	Electric Shock	A0709	Device Sensing Problem		
				A070909	Oversensing		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0709	Device Sensing Problem		

								Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
5917	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT1150	Defibrillators	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT1141	Electrodes/Leads and associated devices	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT1145	Cardiovascular devices	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT233	Surgical	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT2406	Implantable	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT2407	Active implantable	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT258	Implantable defibrillators	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT2727	Active implant devices/ancillaries	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT2866	Implantable cardiac electrical stimulators	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT2985	Active	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT3001	Implantable metal	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT3002	Implantable synthetic polymer	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT3006	Implantable inorganic material	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT3007	Implantable ceramic	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT314	Electrically powered	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT321	Long-term surgical invasive	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT449	Generators and associated devices	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT981	Single use	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
					CT983	Surgical invasive	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem	01/04/2023	01/04/2023
							F1903	Device Explanation	A24	No Apparent Device Problem	01/04/2023	01/04/2023
5918	2023	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A0203	Defective Device	05/07/2024	05/07/2024
									A0709	Device Sensing Problem	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/07/2024	05/07/2024
						F08	Hospitalization or Prolonged Hospitalization	A0203	Defective Device	05/07/2024	05/07/2024	
									A0709	Device Sensing Problem	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/07/2024	05/07/2024
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device	05/07/2024	05/07/2024	
									A0709	Device Sensing Problem	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/07/2024	05/07/2024
						F1905	Device Revision or Replacement	A0203	Defective Device	05/07/2024	05/07/2024	
									A0709	Device Sensing Problem	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/07/2024	05/07/2024
						F2203	Imaging Required	A0203	Defective Device	05/07/2024	05/07/2024	
									A0709	Device Sensing Problem	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/07/2024	05/07/2024
						F23	Unexpected Medical Intervention	A0203	Defective Device	05/07/2024	05/07/2024	
									A0709	Device Sensing Problem	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
5919	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation	05/07/2024	05/07/2024
									A071206	Pacing Asynchronously		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071206	Pacing Asynchronously		
					CT1150	Defibrillators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A071206	Pacing Asynchronously		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A071206	Pacing Asynchronously		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071206	Pacing Asynchronously		
					CT1145	Cardiovascular devices	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A071206	Pacing Asynchronously		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E0601	Arrhythmia	A071206	Pacing Asynchronously		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071206	Pacing Asynchronously		
					CT2406	Implantable	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071206	Pacing Asynchronously		

					CT145	Cardiovascular devices	E2104	Unexpected Diagnostic Intervention	A072201	High Impedance		
							E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT233	Surgical	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT2406	Implantable	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT2407	Active implantable	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT258	Implantable defibrillators	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT2985	Active	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT3001	Implantable metal	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT3007	Implantable ceramic	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT314	Electrically powered	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT449	Generators and associated devices	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT981	Single use	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT983	Surgical invasive	E2104	Electric Shock	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
5024	2023				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
5025	2023				CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
									A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023

							F1905	Device Revision or Replacement	A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
									A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
5926	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/10/2023	23/10/2023
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
5927	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5928	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
									A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/11/2023	23/11/2023
5929	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/12/2023	20/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/12/2023	20/12/2023
									A070504	Premature Discharge of Battery	20/12/2023	20/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/12/2023	20/12/2023
							F1903	Device Implantation	A070504	Premature Discharge of Battery	20/12/2023	20/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/12/2023	20/12/2023
5930	2023				CT258	Implantable defibrillators	E0601	Arrhythmia	A0413	Material Separation		
							F23	Unexpected Medical Intervention	A0413	Material Separation		
5931	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		

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5933	2023	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2023	31/12/2023										
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2023	31/12/2023												
					F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	01/12/2023	31/12/2023												
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2023	31/12/2023												
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2023	31/12/2023										
					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2023	31/12/2023												
					F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	01/12/2023	31/12/2023												
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2023	31/12/2023												
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
							A090801	Signal Artifact/Noise														
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing												
									A090801	Signal Artifact/Noise												
							F2203	Imaging Required	A070909	Oversensing												
									A090801	Signal Artifact/Noise												
							F23	Unexpected Medical Intervention	A070909	Oversensing												
									A090801	Signal Artifact/Noise												
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing												
							A090801	Signal Artifact/Noise														
												F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing							
														A090801	Signal Artifact/Noise							
F2203	Imaging Required	A070909	Oversensing																			
		A090801	Signal Artifact/Noise																			
												F23	Unexpected Medical Intervention	A070909	Oversensing							
														A090801	Signal Artifact/Noise							
										CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
												A090801	Signal Artifact/Noise									
																	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
					F2203	Imaging Required	A070909	Oversensing														
							A090801	Signal Artifact/Noise														
																	F23	Unexpected Medical Intervention	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909											Oversensing							
		A090801	Signal Artifact/Noise																			
																	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
										F2203	Imaging Required	A070909	Oversensing									
												A090801	Signal Artifact/Noise									
																	F23	Unexpected Medical Intervention	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							
							A090801	Signal Artifact/Noise														
																	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
F2203	Imaging Required	A070909	Oversensing																			
		A090801	Signal Artifact/Noise																			
																	F23	Unexpected Medical Intervention	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
										CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
												A090801	Signal Artifact/Noise									
																	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
					F2203	Imaging Required	A070909	Oversensing														
							A090801	Signal Artifact/Noise														
																	F23	Unexpected Medical Intervention	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909											Oversensing							
		A090801	Signal Artifact/Noise																			
																	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
										F2203	Imaging Required	A070909	Oversensing									
												A090801	Signal Artifact/Noise									
																	F23	Unexpected Medical Intervention	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							
							A090801	Signal Artifact/Noise														
																	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
F2203	Imaging Required	A070909	Oversensing																			
		A090801	Signal Artifact/Noise																			
																	F23	Unexpected Medical Intervention	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
										CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing							
												A090801	Signal Artifact/Noise									
																	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
					F2203	Imaging Required	A070909	Oversensing														
							A090801	Signal Artifact/Noise														
																	F23	Unexpected Medical Intervention	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909											Oversensing							
		A090801	Signal Artifact/Noise																			
																	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
										F2203	Imaging Required	A070909	Oversensing									
												A090801	Signal Artifact/Noise									
																	F23	Unexpected Medical Intervention	A070909	Oversensing		
																			A090801	Signal Artifact/Noise		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909						Oversensing							

				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
		F2203	Imaging Required	A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F2203	Imaging Required	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
		F23	Unexpected Medical Intervention	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
						F2203	Imaging Required	A070909	Signal Artifact/Noise		
						F23	Unexpected Medical Intervention	A090801	Overensing		
								A090801	Signal Artifact/Noise		
					CT1981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
						F2203	Imaging Required	A090801	Signal Artifact/Noise		
						F23	Unexpected Medical Intervention	A070909	Overensing		
								A090801	Signal Artifact/Noise		
					CT1983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing	
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
						F2203	Imaging Required	A090801	Signal Artifact/Noise		
						F23	Unexpected Medical Intervention	A070909	Overensing		
								A090801	Signal Artifact/Noise		
5934	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	
						F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	
						F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm	
						F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
5935	2023	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT11147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT12406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT12407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023

							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT449	Generators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT981	Single use	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/09/2023	15/09/2023
5936	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
5937	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A160601	Premature Elective Replacement Indicator		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A160601	Premature Elective Replacement Indicator		
5938	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/03/2024	11/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/03/2024	11/03/2024
5939	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E011903	Syncope/Fainting	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2311	Discomfort	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E011903	Syncope/Fainting	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2311	Discomfort	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E011903	Syncope/Fainting	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2311	Discomfort	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E011903	Syncope/Fainting	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

						E2311	Discomfort	A070909	Oversensing		
						E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting	A070909	Oversensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2311	Discomfort	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2330	Pain	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
5940	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	23/05/2023
								A070909	Oversensing		23/05/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/05/2023	23/05/2023
						F2203	Imaging Required	A070909	Oversensing	23/05/2023	23/05/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	23/05/2023
								A070909	Oversensing	23/05/2023	23/05/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/05/2023	23/05/2023
						F2203	Imaging Required	A070909	Oversensing	23/05/2023	23/05/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	23/05/2023
								A070909	Oversensing	23/05/2023	23/05/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/05/2023	23/05/2023
						F2203	Imaging Required	A070909	Oversensing	23/05/2023	23/05/2023
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	23/05/2023
								A070909	Oversensing	23/05/2023	23/05/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/05/2023	23/05/2023
						F2203	Imaging Required	A070909	Oversensing	23/05/2023	23/05/2023
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	23/05/2023
								A0709	Device Sensing Problem	23/05/2023	23/05/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	23/05/2023	23/05/2023
						F2203	Imaging Required	A0709	Device Sensing Problem	23/05/2023	23/05/2023
					CT1233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	23/05/2023
								A0709	Device Sensing Problem	23/05/2023	23/05/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	23/05/2023	23/05/2023
						F2203	Imaging Required	A0709	Device Sensing Problem	23/05/2023	23/05/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	23/05/2023
								A0709	Device Sensing Problem	23/05/2023	23/05/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	23/05/2023	23/05/2023
						F2203	Imaging Required	A0709	Device Sensing Problem	23/05/2023	23/05/2023
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	23/05/2023
								A0709	Device Sensing Problem	23/05/2023	23/05/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	23/05/2023	23/05/2023</

						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT2727	Active implant devices/ancillaries	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT2750	Implantable cardiac electrical stimulators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT2966	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT2985	Active	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT3001	Implantable metal	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT3002	Implantable synthetic polymer	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT3006	Implantable inorganic material	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT3007	Implantable ceramic	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT314	Electrically powered	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT321	Long-term surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT449	Generators and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT981	Single use	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						CT983	Surgical invasive	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
5945	2023					CT258	Implantable defibrillators			A071205	Pacemaker Found in Back-Up Mode		
5946	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023	
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
								A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
								A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
						F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		

C12406	Implantable	E2104	Electric Shock	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
C12407	Active implantable	E2104	Electric Shock	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
C1258	Implantable defibrillators	E2104	Electric Shock	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
C12727	Active implant devices/ancillaries	E2104	Electric Shock	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
C12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
C12866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
C12985	Active	E2104	Electric Shock	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
		F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
		A090801	Signal Artifact/Noise	23/10/2023	23/10/2023		
		A1301	Failure to Read Input Signal	23/10/2023	23/10/2023		
		A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023		
C13001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023
				A1301	Failure to Read Input Signal	23/10/2023	23/10/2023
				A090801	Signal Artifact/Noise	23/10/2023	23/10/2023

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							F1905	Device Revision or Replacement	A071302 A090801 A1301	Failure to Read Input Signal Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	23/10/2023 23/10/2023 23/10/2023	23/10/2023 23/10/2023 23/10/2023
					CT1983	Surgical invasive	E2104	Electric Shock	A071302 A090801 A1301	Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	23/10/2023 23/10/2023 23/10/2023	23/10/2023 23/10/2023 23/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302 A090801 A1301	Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	23/10/2023 23/10/2023 23/10/2023	23/10/2023 23/10/2023 23/10/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A090801 A1301	Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	23/10/2023 23/10/2023 23/10/2023	23/10/2023 23/10/2023 23/10/2023
							F1905	Device Revision or Replacement	A071302 A090801 A1301	Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	23/10/2023 23/10/2023 23/10/2023	23/10/2023 23/10/2023 23/10/2023
5947	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
5948	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070910 A0712	Undersensing Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A0712	Undersensing Pacing Problem		

					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
5949	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0119	Loss of Consciousness	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E060102	Atrial Fibrillation	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm		
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2301	Additional Device Required	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E0119	Loss of Consciousness	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E060102	Atrial Fibrillation	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2301	Additional Device Required	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0119	Loss of Consciousness	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E060102	Atrial Fibrillation	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1901	Additional Surgery	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2301	Additional Device Required	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
5950	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2024	25/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/01/2024	25/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2024	25/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/01/2024	25/01/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2024	25/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/01/2024	25/01/2024
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2024	25/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/01/2024	25/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2024	25/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/01/2024	25/01/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/01/2024	25/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/01/2024	25/01/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/01/2024	25/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/01/2024	25/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/01/2024	25/01/2024

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							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
5954	2023		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
5955	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
5956	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/02/2024	12/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/02/2024	12/02/2024
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	12/02/2024	12/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/02/2024	12/02/2024
5957	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/11/2023	23/11/2023
5958	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
5959	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A0709	Device Sensing Problem		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A0709	Device Sensing Problem		
									A070910	Undersensing		

						F26	No Health Consequences or Impact	A1301 A0709 A070910 A1301	Failure to Read Input Signal Device Sensing Problem Undersensing Failure to Read Input Signal		
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070910 A1301	Device Sensing Problem Undersensing Failure to Read Input Signal		
					F2203	Imaging Required	A0709 A070910 A1301	Device Sensing Problem Undersensing Failure to Read Input Signal			
					F26	No Health Consequences or Impact	A0709 A070910 A1301	Device Sensing Problem Undersensing Failure to Read Input Signal			
				CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1301 A0709 A1301	Failure to Read Input Signal Device Sensing Problem Undersensing		
					F2203	Imaging Required	A0709 A070910 A1301	Device Sensing Problem Undersensing Failure to Read Input Signal			
					F26	No Health Consequences or Impact	A0709 A070910 A1301	Device Sensing Problem Undersensing Failure to Read Input Signal			
				CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070910 A1301	Device Sensing Problem Undersensing Failure to Read Input Signal		
					F2203	Imaging Required	A0709 A070910 A1301	Device Sensing Problem Undersensing Failure to Read Input Signal			
					F26	No Health Consequences or Impact	A0709 A070910 A1301	Device Sensing Problem Undersensing Failure to Read Input Signal			
5960	2023	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A1301 A070909 A071302 A090801 A1301	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
5961	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	18/12/2023 18/12/2023 18/12/2023
					F08	Hospitalization or Prolonged Hospitalization	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	18/12/2023 18/12/2023 18/12/2023	18/12/2023 18/12/2023 18/12/2023	
					F1905	Device Revision or Replacement	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	18/12/2023 18/12/2023 18/12/2023	18/12/2023 18/12/2023 18/12/2023	
5962	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery	
				CT1150	Defibrillators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery		
				CT258	Implantable defibrillators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery		
				CT263	Cardiographs and associated devices	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery		
				CT2866	Implantable cardiac electrical stimulators	E2403 F1901	No Clinical Signs, Symptoms or Conditions Additional Surgery	A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery		
5963	2023		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401 F02	Insufficient Information Death	A070910 A070910	Undersensing Undersensing	
				CT1150	Defibrillators	E2401 F02	Insufficient Information Death	A070910 A070910	Undersensing Undersensing		
				CT258	Implantable defibrillators	E2401 F02	Insufficient Information Death	A070910 A070910	Undersensing Undersensing		
				CT263	Cardiographs and associated devices	E2401 F02	Insufficient Information Death	A070910 A070910	Undersensing Undersensing		
				CT2866	Implantable cardiac electrical stimulators	E2401 F02	Insufficient Information Death	A070910 A070910	Undersensing Undersensing		
5964	2023	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	21/08/2023 21/08/2023 21/08/2023
					F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	21/08/2023 21/08/2023 21/08/2023	21/08/2023 21/08/2023 21/08/2023	
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	21/08/2023 21/08/2023 21/08/2023	21/08/2023 21/08/2023 21/08/2023	
					F1905	Device Revision or Replacement	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	21/08/2023 21/08/2023 21/08/2023	21/08/2023 21/08/2023 21/08/2023	
5965	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403 F08 F1903	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Device Explication	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024 09/01/2024 09/01/2024 09/01/2024
				CT1150	Defibrillators	E2403 F08	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024 09/01/2024	09/01/2024 09/01/2024

							F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
									A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
9966	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
9967	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
9968	2023	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
9969	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A0709 A070909 A071302 A1301	Failure to Read Input Signal Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
5970	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
5971	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
							F13	Misdiagnosis/ Misclassification	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation			

									A071302	Inappropriate/Inadequate Shock/Stimulation	17/11/2023	17/11/2023
							F1903	Device Explanation	A16	Protective Measures Problem	17/11/2023	17/11/2023
									A0712	Pacing Problem	17/11/2023	17/11/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/11/2023	17/11/2023
						CT2866		Implantable cardiac electrical stimulators	A16	Protective Measures Problem	17/11/2023	17/11/2023
							E210401	Shock from Patient Lead(s)	A0712	Pacing Problem	17/11/2023	17/11/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/11/2023	17/11/2023
									A16	Protective Measures Problem	17/11/2023	17/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem	17/11/2023	17/11/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/11/2023	17/11/2023
									A16	Protective Measures Problem	17/11/2023	17/11/2023
							F1203	Life Threatening Illness or Injury	A0712	Pacing Problem	17/11/2023	17/11/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/11/2023	17/11/2023
									A16	Protective Measures Problem	17/11/2023	17/11/2023
							F1903	Device Explanation	A0712	Pacing Problem	17/11/2023	17/11/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	17/11/2023	17/11/2023
									A16	Protective Measures Problem	17/11/2023	17/11/2023
5973	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
						CT1150		Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
						CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
						CT263		Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
						CT2866		Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
5974	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT1147		Defibrillators and associated devices	A1301	Failure to Read Input Signal		
							E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
						CT1150		Defibrillators	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2104	Electric Shock	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						CT141		Electrodes/Leads and associated devices	A070909	Oversensing		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						CT145		Cardiovascular devices	A070909	Oversensing		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						CT233		Surgical	A070909	Oversensing		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						CT2406		Implantable	A070909	Oversensing		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						CT2407		Active implantable	A070909	Oversensing		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						CT258		Implantable defibrillators	A070909	Oversensing		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						CT263		Cardiographs and associated devices	E2104	Electric Shock		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT2985	Active	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT3001	Implantable metal	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT3007	Implantable ceramic	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT314	Electrically powered	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT449	Generators and associated devices	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT981	Single use	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT983	Surgical invasive	E2104	Electric Shock	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
5975	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070602 A0908	Delayed Charge Time Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024 26/09/2024	26/09/2024 26/09/2024

							F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	26/09/2024	26/09/2024
							F1001	Absence of Treatment	A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
									A070602	Delayed Charge Time	26/09/2024	26/09/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
									A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
						CT258	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
							F1001	Absence of Treatment	A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
						CT2866	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
							F1001	Absence of Treatment	A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time	26/09/2024	26/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/09/2024	26/09/2024
5976	2023	All other reportable incidents				CT258	E2104	Electric Shock	A070909	Oversensing	29/02/2024	29/02/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	29/02/2024	29/02/2024
									A090801	Signal Artifact/Noise	29/02/2024	29/02/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	29/02/2024	29/02/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	29/02/2024	29/02/2024
									A090801	Signal Artifact/Noise	29/02/2024	29/02/2024
5977	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
5979	2023	Death	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1141	Electrodes/Leads and associated devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1145	Cardiovascular devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1233	Surgical	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2406	Implantable	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2407	Active implantable	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2727	Active implant devices/ancillaries	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2806	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2985	Active	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3001	Implantable metal	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT3002	Implantable synthetic polymer	E2401	Insufficient Information	A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A071201	Failure to Convert Rhythm		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		

							CT3006	Implantable inorganic material	E2401	Insufficient Information	A071201	Failure to Convert Rhythm			
							F02		Death	A072201	High Impedance				
							CT3007		Implantable ceramic	E2401	Insufficient Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
												A071201	Failure to Convert Rhythm		
												A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings				
										F02	Death	A071201	Failure to Convert Rhythm		
										A072201	High Impedance				
							CT314		Electrically powered	E2401	Insufficient Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
												A071201	Failure to Convert Rhythm		
												A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings				
										F02	Death	A071201	Failure to Convert Rhythm		
										A072201	High Impedance				
							CT321		Long-term surgical invasive	E2401	Insufficient Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
												A071201	Failure to Convert Rhythm		
												A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings				
										F02	Death	A071201	Failure to Convert Rhythm		
										A072201	High Impedance				
							CT449		Generators and associated devices	E2401	Insufficient Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
												A071201	Failure to Convert Rhythm		
												A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings				
F02	Death	A071201	Failure to Convert Rhythm												
A072201	High Impedance														
CT981	Single use	E2401	Insufficient Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings										
				A071201	Failure to Convert Rhythm										
				A072201	High Impedance										
		A0908	Incorrect, Inadequate or Imprecise Result or Readings												
		F02	Death	A071201	Failure to Convert Rhythm										
		A072201	High Impedance												
CT983	Surgical invasive	E2401	Insufficient Information	A0908	Incorrect, Inadequate or Imprecise Result or Readings										
				A071201	Failure to Convert Rhythm										
				A072201	High Impedance										
		A0908	Incorrect, Inadequate or Imprecise Result or Readings												
		F02	Death	A071201	Failure to Convert Rhythm										
		A072201	High Impedance												
9980	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/12/2023	15/12/2023			
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/12/2023	15/12/2023					
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/12/2023	15/12/2023			
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/12/2023	15/12/2023					
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/12/2023	15/12/2023			
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/12/2023	15/12/2023					
							A0705	Battery Problem	07/02/2024	07/02/2024					
							A070504	Premature Discharge of Battery	07/02/2024	07/02/2024					
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/02/2024	07/02/2024					
							A0705	Battery Problem	07/02/2024	07/02/2024					
							A070504	Premature Discharge of Battery	07/02/2024	07/02/2024					
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/02/2024	07/02/2024					
9981	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/02/2024	07/02/2024			
							A070504	Premature Discharge of Battery	07/02/2024	07/02/2024					
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/02/2024	07/02/2024					
							A0705	Battery Problem	07/02/2024	07/02/2024					
							A070504	Premature Discharge of Battery	07/02/2024	07/02/2024					
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/02/2024	07/02/2024					
							F1903	Device Explantation	A0705	Battery Problem	07/02/2024	07/02/2024			
							A070504	Premature Discharge of Battery	07/02/2024	07/02/2024					
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/02/2024	07/02/2024					
							A0709	Device Sensing Problem							
							A070909	Overensing							
							A071302	Inappropriate/Inadequate Shock/Stimulation							
9982	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem					
							A070909	Overensing							
							A071302	Inappropriate/Inadequate Shock/Stimulation							
							A1301	Failure to Read Input Signal							
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem					
							A070909	Overensing							
							A071302	Inappropriate/Inadequate Shock/Stimulation							
							A1301	Failure to Read Input Signal							
							F2203	Imaging Required	A0709	Device Sensing Problem					
							A070909	Overensing							
							A071302	Inappropriate/Inadequate Shock/Stimulation							
							A1301	Failure to Read Input Signal							
							CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem			
											A070909	Overensing			
											A071302	Inappropriate/Inadequate Shock/Stimulation			
									A1301	Failure to Read Input Signal					
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Overensing					
							A071302	Inappropriate/Inadequate Shock/Stimulation							
							A1301	Failure to Read Input Signal							
							F2203	Imaging Required	A0709	Device Sensing Problem					
							A070909	Overensing							
							A071302	Inappropriate/Inadequate Shock/Stimulation							
							A1301	Failure to Read Input Signal							
CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem										
				A070909	Overensing										
				A071302	Inappropriate/Inadequate Shock/Stimulation										
		A1301	Failure to Read Input Signal												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem										
		A070909	Overensing												
A071302	Inappropriate/Inadequate Shock/Stimulation														
A1301	Failure to Read Input Signal														

							F2203	Imaging Required	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F2203	Imaging Required	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F2203	Imaging Required	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
5983	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102 A070909 A0712 A071302 A0722 A1301	High Capture Threshold Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Impedance Problem Failure to Read Input Signal		
5984	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		

					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5985	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1147	Defibrillators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1141	Electrodes/Leads and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1145	Cardiovascular devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1233	Surgical	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		

					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
CT263	Cardiographs and associated devices	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT2726	Physiological monitoring/measuring devices	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT2727	Active implant devices/ancillaries	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT2985	Active	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT3001	Implantable metal	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT3002	Implantable synthetic polymer	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT3006	Implantable inorganic material	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
		F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing					
			A071302	Inappropriate/Inadequate Shock/Stimulation					
			A1301	Failure to Read Input Signal					
CT3007	Implantable ceramic	E2104	Electric Shock		A070909	Oversensing			
					A071302	Inappropriate/Inadequate Shock/Stimulation			
					A1301	Failure to Read Input Signal			
					A071302	Inappropriate/Inadequate Shock/Stimulation			

							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1314	Electrically powered	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT321	Long-term surgical invasive	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT449	Generators and associated devices	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT981	Single use	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT983	Surgical invasive	E2104	Electric Shock	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
5986	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024

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						F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	Premature Discharge of Battery	09/01/2024	09/01/2024
						F1903	Device Explanation	A070504	Incorrect, Inadequate or Imprecise Result or Readings	Premature Discharge of Battery	09/01/2024	09/01/2024
					CT981	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	Premature Discharge of Battery	09/01/2024	09/01/2024
						F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	Premature Discharge of Battery	09/01/2024	09/01/2024
						F1903	Device Explanation	A070504	Incorrect, Inadequate or Imprecise Result or Readings	Premature Discharge of Battery	09/01/2024	09/01/2024
					CT983	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	Premature Discharge of Battery	09/01/2024	09/01/2024
						F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	Premature Discharge of Battery	09/01/2024	09/01/2024
						F1903	Device Explanation	A070504	Incorrect, Inadequate or Imprecise Result or Readings	Premature Discharge of Battery	09/01/2024	09/01/2024
5987	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT1150	E2403	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT258	E2403	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT263	E2403	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
					CT2866	E2403	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
5988	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
					CT1150	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
					CT1141	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
					CT1145	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
					CT233	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
					CT2406	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/06/2023	23/06/2023	

5991	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	F15	Recognized Device or Procedural Complication	A070909	Oversensing		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1010	Cardiovascular physiology analysis/mapping devices	F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5992	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
5993	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
					CT1150	Defibrillators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
5994	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/01/2024	10/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/01/2024	10/01/2024
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	10/01/2024	10/01/2024
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
5995	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
5996	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
5997	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A070909	Oversensing		
									A070909	Oversensing		
					CT2408	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2409	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		

					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
5998	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT11150	Defibrillators	F1001	Absence of Treatment	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F1001	Absence of Treatment	A0712	Pacing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F1001	Absence of Treatment	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F1001	Absence of Treatment	A0712	Pacing Problem		
5999	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
					CT11150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
					CT1258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
					CT1263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
6000	2023	All other reportable incidents			CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
6001	2023	All other reportable incidents			CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
6002	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
6003	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E060101	Asystole	A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F1001	Absence of Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
6004	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal			
									A070909	Oversensing			
									A070910	Undersensing			
									A072202	Low Impedance			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
8005	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	07/12/2023	07/12/2023	
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	07/12/2023	07/12/2023	
							F1905	Device Revision or Replacement	A072201	High Impedance	07/12/2023	07/12/2023	
8006	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT141	Electrodes/Leads and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT145	Cardiovascular devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2727	Active implant devices/ancillaries	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2985	Active	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3001	Implantable metal	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3002	Implantable synthetic polymer	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3006	Implantable inorganic material	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT3007	Implantable ceramic	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT314	Electrically powered	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT321	Long-term surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT449	Generators and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			

						CT981	Single use	F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
						CT983	Surgical invasive	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
						CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
										A070504	Premature Discharge of Battery	05/06/2023	05/06/2023

					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
									A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
									A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
									A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
									A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
									A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
									A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/06/2023	05/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/06/2023	05/06/2023
									A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
8008	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/06/2023	05/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/03/2024	21/03/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/03/2024	21/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/03/2024	21/03/2024
8009	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	13/12/2023	13/12/2023
8010	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060106	Heart Block	A0712	Pacing Problem		
							F12	Serious Injury/Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E060106	Heart Block	A0712	Pacing Problem		
							F12	Serious Injury/Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060106	Heart Block	A0712	Pacing Problem		
							F12	Serious Injury/Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
8011	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		

8012	2023	All other reportable incidents	36852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F1903	Device Explanation	A070504	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
8013	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/12/2023	01/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/12/2023	01/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/12/2023	01/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/12/2023	01/12/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/12/2023	01/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/12/2023	01/12/2023
8014	2023	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060101	Asystole	A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
8015	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8016	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/08/2024	01/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/08/2024	01/08/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/08/2024	01/08/2024
									A070504	Premature Discharge of Battery	01/08/2024	01/08/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/08/2024	01/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/08/2024	01/08/2024
8017	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
									A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
					CT258	Implantable defibrillators	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
									A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	21/12/2023	21/12/2023
8018	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E1032	Vomiting	A070102	High Capture Threshold		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102	High Capture Threshold		
									A070909	Oversensing		

										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
						F2203	Imaging Required			A070102	High Capture Threshold		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E1032	Vomiting		A070102	High Capture Threshold		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070102	High Capture Threshold		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
							F2203	Imaging Required		A070102	High Capture Threshold		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E1032	Vomiting		A070102	High Capture Threshold		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070102	High Capture Threshold		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
							F2203	Imaging Required		A070102	High Capture Threshold		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
0019	2023		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT1147	Defibrillators and associated devices	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT1150	Defibrillators	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT141	Electrodes/Leads and associated devices	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT145	Cardiovascular devices	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT233	Surgical	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT2406	Implantable	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT2407	Active implantable	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT258	Implantable defibrillators	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT263	Cardiographs and associated devices	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT2726	Physiological monitoring/measuring devices	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT2727	Active implant devices/ancillaries	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT2750	Implantable cardiac electrical stimulators and associated devices	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT2866	Implantable cardiac electrical stimulators	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT2985	Active	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT3001	Implantable metal	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT3002	Implantable synthetic polymer	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT3006	Implantable inorganic material	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT3007	Implantable ceramic	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT314	Electrically powered	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT321	Long-term surgical invasive	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT440	Generators and associated devices	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT981	Single use	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
					CT983	Surgical invasive	F05	Delay to Treatment/ Therapy		A0203	Defective Device		
0020	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0722	Impedance Problem	30/07/2024	30/07/2024
							F08	Hospitalization or Prolonged Hospitalization		A0722	Impedance Problem	30/07/2024	30/07/2024
							F1905	Device Revision or Replacement		A0722	Impedance Problem	30/07/2024	30/07/2024
0021	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
									A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
8022	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
8023	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
8024	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	Tachycardia	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E060109	Tachycardia	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		

6025	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024					
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024					
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024					
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024					
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024					
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024					
		CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024								
				F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024								
				F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024								
				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024								
				F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024								
				F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024								
	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024									
			F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024									
			F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024									
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024									
			F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024									
			F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024									
	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024									
			F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024									
			F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024									
			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024									
			F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024									
			F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024									
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024										
		F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024										
		F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024										
		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024										
		F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	01/01/2024	01/01/2024										
		F1903	Device Explanation	A070504	Premature Discharge of Battery	01/01/2024	01/01/2024										
6026	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
							F26	No Health Consequences or Impact	A072201	High Impedance							
							CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance					
									F26	No Health Consequences or Impact	A072201	High Impedance					
							CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance					
									F26	No Health Consequences or Impact	A072201	High Impedance					
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
							F26	No Health Consequences or Impact	A072201	High Impedance							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
							F26	No Health Consequences or Impact	A072201	High Impedance							
					6027	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing		
												F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
F15	Recognized Device or Procedural Complication	A070909	Oversensing														
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation														
F15	Recognized Device or Procedural Complication	A070909	Oversensing														
F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation														
CT1150	Defibrillators	E2104	Electric Shock	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation							
		F15	Recognized Device or Procedural Complication	A070909						Oversensing							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302						Inappropriate/Inadequate Shock/Stimulation							
		F15	Recognized Device or Procedural Complication	A070909						Oversensing							
		F15	Recognized Device or Procedural Complication	A071302						Inappropriate/Inadequate Shock/Stimulation							
CT258	Implantable defibrillators	E2104	Electric Shock	A070909		Oversensing											
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302		Inappropriate/Inadequate Shock/Stimulation											
		F15	Recognized Device or Procedural Complication	A070909		Oversensing											
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302		Inappropriate/Inadequate Shock/Stimulation											
		F15	Recognized Device or Procedural Complication	A070909		Oversensing											
		F15	Recognized Device or Procedural Complication	A071302		Inappropriate/Inadequate Shock/Stimulation											
CT263	Cardiographs and associated devices	E2104	Electric Shock	A070909		Oversensing											
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302		Inappropriate/Inadequate Shock/Stimulation											
		F15	Recognized Device or Procedural Complication	A070909		Oversensing											
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302		Inappropriate/Inadequate Shock/Stimulation											
		F15	Recognized Device or Procedural Complication	A070909		Oversensing											
		F15	Recognized Device or Procedural Complication	A071302		Inappropriate/Inadequate Shock/Stimulation											
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation												
		F15	Recognized Device or Procedural Complication	A070909	Oversensing												
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation												
		F15	Recognized Device or Procedural Complication	A070909	Oversensing												
		F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation												
6028	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing							
									A070910	Undersensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation							
									A070801	Signal Artifact/Noise							
									A070909	Oversensing							
									A070910	Undersensing							
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation							
									A070910	Undersensing							
									A071302	Inappropriate/Inadequate Shock/Stimulation							
									A070801	Signal Artifact/Noise							
									A070909	Oversensing							
									A070910	Undersensing							
F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation														
		A070910	Undersensing														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A070801	Signal Artifact/Noise														
		A070909	Oversensing														
		A070910	Undersensing														
CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing												
				A070910	Undersensing												
				A071302	Inappropriate/Inadequate Shock/Stimulation												
				A070801	Signal Artifact/Noise												
				A070909	Oversensing												
				A070910	Undersensing												
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation														
		A070910	Undersensing														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A070910	Undersensing														
		A071302	Inappropriate/Inadequate Shock/Stimulation														
		A070910	Undersensing														

							F15	Recognized Device or Procedural Complication	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A090801 A070909 A070910 A071302	Signal Artifact/Noise Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
8029	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
8030	2024	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A040101 A070909 A071302	Fracture Oversensing Inappropriate/Inadequate Shock/Stimulation	04/01/2024 04/01/2024 04/01/2024	04/01/2024 04/01/2024 04/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A040101 A070909 A071302	Fracture Oversensing Inappropriate/Inadequate Shock/Stimulation	04/01/2024 04/01/2024 04/01/2024	04/01/2024 04/01/2024 04/01/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A040101 A070909 A071302	Fracture Oversensing Inappropriate/Inadequate Shock/Stimulation	04/01/2024 04/01/2024 04/01/2024	04/01/2024 04/01/2024 04/01/2024
							F15	Recognized Device or Procedural Complication	A040101 A070909 A071302	Fracture Oversensing Inappropriate/Inadequate Shock/Stimulation	04/01/2024 04/01/2024 04/01/2024	04/01/2024 04/01/2024 04/01/2024
							F1905	Device Revision or Replacement	A040101 A070909 A071302	Fracture Oversensing Inappropriate/Inadequate Shock/Stimulation	04/01/2024 04/01/2024 04/01/2024	04/01/2024 04/01/2024 04/01/2024
8031	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302 A070101 A072201	Failure to Capture Failure to Capture High Impedance	04/01/2024	04/01/2024
							F2203	Imaging Required	A090801 A070101 A072201	Signal Artifact/Noise Failure to Capture High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801 A070101 A072201	Signal Artifact/Noise Failure to Capture High Impedance		
							F2203	Imaging Required	A090801 A070101 A072201	Signal Artifact/Noise Failure to Capture High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090801 A070101 A072201	Signal Artifact/Noise Failure to Capture High Impedance		
							F2203	Imaging Required	A090801 A070101 A072201	Signal Artifact/Noise Failure to Capture High Impedance		
8032	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem		
							E1707	Impaired Healing	A24	No Apparent Device Problem		
					CT1150	Defibrillators	F15	Recognized Device or Procedural Complication	A24	No Apparent Device Problem		
							E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem		
							E1707	Impaired Healing	A24	No Apparent Device Problem		

					CT258	Implantable defibrillators	E0402	Recognized Device or Procedural Complication	A24	No Apparent Device Problem		
							E1707	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem		
							F15	Impaired Healing	A24	No Apparent Device Problem		
					CT263	Cardiographs and associated devices	F15	Recognized Device or Procedural Complication	A24	No Apparent Device Problem		
							E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem		
							E1707	Impaired Healing	A24	No Apparent Device Problem		
					CT2866	Implantable cardiac electrical stimulators	F15	Recognized Device or Procedural Complication	A24	No Apparent Device Problem		
							E0402	Hypersensitivity/Allergic Reaction	A24	No Apparent Device Problem		
							E1707	Impaired Healing	A24	No Apparent Device Problem		
							F15	Recognized Device or Procedural Complication	A24	No Apparent Device Problem		
8033	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
8034	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
8035	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/01/2024	18/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/04/2024	18/04/2024
							F1005	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/04/2024	18/04/2024
8036	2024	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8037	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060110	Ventricular Fibrillation	A070910	Undersensing	01/01/2024	01/01/2024
									A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	01/01/2024	01/01/2024
							F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
									A070910	Undersensing	01/01/2024	01/01/2024
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
									A070910	Undersensing	01/01/2024	01/01/2024
					CT1150	Defibrillators	E060110	Ventricular Fibrillation	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
									A070910	Undersensing	01/01/2024	01/01/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	01/01/2024	01/01/2024
									A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
							F15	Recognized Device or Procedural Complication	A070910	Undersensing	01/01/2024	01/01/2024
									A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
					CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A070910	Undersensing	01/01/2024	01/01/2024
									A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing	01/01/2024	01/01/2024
							F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
									A070910	Undersensing	01/01/2024	01/01/2024
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
									A070910	Undersensing	01/01/2024	01/01/2024
					CT263	Cardiographs and associated devices	E060110	Ventricular Fibrillation	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
									A070910	Undersensing	01/01/2024	01/01/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	01/01/2024	01/01/2024
									A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
							F15	Recognized Device or Procedural Complication	A070910	Undersensing	01/01/2024	01/01/2024
									A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
					CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
									A070910	Undersensing	01/01/2024	01/01/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
							F1203	Life Threatening Illness or Injury	A070910	Undersensing	01/01/2024	01/01/2024
									A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
							F15	Recognized Device or Procedural Complication	A070910	Undersensing	01/01/2024	01/01/2024
									A071202	Inaccurate Synchronization	01/01/2024	01/01/2024
8038	2024	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A0203	Defective Device	20/10/2023	20/10/2023

									A040101	Fracture	2010/2023	2010/2023
									A070909	Oversensing	2010/2023	2010/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	2010/2023	2010/2023
						F08	Hospitalization or Prolonged Hospitalization		A0203	Defective Device	2010/2023	2010/2023
									A040101	Fracture	2010/2023	2010/2023
									A070909	Oversensing	2010/2023	2010/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	2010/2023	2010/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0203	Defective Device	2010/2023	2010/2023
									A040101	Fracture	2010/2023	2010/2023
									A070909	Oversensing	2010/2023	2010/2023
						F1903	Device Explanation		A071302	Inappropriate/Inadequate Shock/Stimulation	2010/2023	2010/2023
									A0203	Defective Device	2010/2023	2010/2023
									A040101	Fracture	2010/2023	2010/2023
									A070909	Oversensing	2010/2023	2010/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	2010/2023	2010/2023
6039	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
						F22	Unexpected Diagnostic Intervention	A070909	Oversensing			
									A071204	No Pacing		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		

							F22	Unexpected Diagnostic Intervention	A070909	Oversensing		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A071204	No Pacing		
							F22	Unexpected Diagnostic Intervention	A070909	Oversensing		
							F22	Unexpected Diagnostic Intervention	A071204	No Pacing		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F22	Unexpected Diagnostic Intervention	A071204	No Pacing		
							F22	Unexpected Diagnostic Intervention	A070909	Oversensing		
							F22	Unexpected Diagnostic Intervention	A071204	No Pacing		
8040	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8041	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	16/03/2023	16/03/2023
8042	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
									A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
									A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
							F1905	Device Revision or Replacement	A070504	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
									A0908	Premature Discharge of Battery	06/03/2024	06/03/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/03/2024	06/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/03/2024	06/03/2024
8043	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
8044	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
8045	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/05/2024	02/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/05/2024	02/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/05/2024	02/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/05/2024	02/05/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	02/05/2024	02/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	02/05/2024	02/05/2024
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8046	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8047	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
							F26	No Health Consequences or Impact	A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
							F26	No Health Consequences or Impact	A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
							F26	No Health Consequences or Impact	A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
							F26	No Health Consequences or Impact	A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0202	Defective Component		

							F26	No Health Consequences or Impact	A07	Electrical /Electronic Property Problem		
									A0202	Defective Component		
									A07	Electrical /Electronic Property Problem		
8048	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/02/2024	07/02/2024
8049	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
8050	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
8051	2024	All other reportable incidents			CT258	Implantable defibrillators	E060104	Bradycardia	A070909	Oversensing		
									A0712	Pacing Problem		
							F1001	Absence of Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
8052	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8053	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/11/2023	02/11/2023
									A070504	Premature Discharge of Battery	02/11/2023	02/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/11/2023	02/11/2023
									A070504	Premature Discharge of Battery	02/11/2023	02/11/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	02/11/2023	02/11/2023
									A070504	Premature Discharge of Battery	02/11/2023	02/11/2023
8054	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
8055	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

							F26	No Health Consequences or Impact	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery		
6056	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A071302	Inappropriate/Inadequate Shock/Stimulation		
6057	2024	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							E060110	Ventricular Fibrillation	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							F02	Death	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							F0801	Intensive Care	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							F23	Unexpected Medical Intervention	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							F2306	Resuscitation	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
					CT1150	Defibrillators	E060109	Tachycardia	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							E060110	Ventricular Fibrillation	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							F02	Death	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							F0801	Intensive Care	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0401 A0713 A072201 A072202	Break Defibrillation/Stimulation Problem High Impedance Low Impedance		

							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			
							A0401	Break			
							A0713	Defibrillation/Stimulation Problem			
							A072201	High Impedance			
							A072202	Low Impedance			
							A09	Output Problem			
							A090805	Incorrect Measurement			

							F2306	Resuscitation	A072202 A09 A090805 A0401 A0713 A072201 A072202 A09 A090805	Low Impedance Output Problem Incorrect Measurement Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement		
				CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0401 A0713 A072201 A072202 A09 A090805	Low Impedance Output Problem Incorrect Measurement Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem			
						E060110	Ventricular Fibrillation	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement			
						F02	Death	A0401 A0713 A072201 A072202 A09 A090805	Incorrect Measurement Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem			
						F0801	Intensive Care	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement			
						F23	Unexpected Medical Intervention	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement			
						F2306	Resuscitation	A0401 A0713 A072201 A072202 A09 A090805	Break Defibrillation/Stimulation Problem High Impedance Low Impedance Output Problem Incorrect Measurement			
8058	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403 F08 F12 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Serious Injury/ Illness/ Impairment Device Revision or Replacement	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	01/12/2023 01/12/2023 01/12/2023 01/12/2023	31/12/2023 31/12/2023 31/12/2023 31/12/2023
					CT258	Implantable defibrillators	E2403 F08 F12 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Serious Injury/ Illness/ Impairment Device Revision or Replacement	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	01/12/2023 01/12/2023 01/12/2023 01/12/2023	31/12/2023 31/12/2023 31/12/2023 31/12/2023
					CT2866	Implantable cardiac electrical stimulators	E2403 F08 F12 F1905	No Clinical Signs, Symptoms or Conditions Hospitalization or Prolonged Hospitalization Serious Injury/ Illness/ Impairment Device Revision or Replacement	A070504 A070504 A070504 A070504	Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery Premature Discharge of Battery	01/12/2023 01/12/2023 01/12/2023 01/12/2023	31/12/2023 31/12/2023 31/12/2023 31/12/2023
8059	2024	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401 F02 F10 F1203 F23	Shock from Patient Lead(s) Death Inadequate/Inappropriate Treatment or Diagnostic Exposure Life Threatening Illness or Injury Unexpected Medical Intervention	A0709 A071302 A090811 A0709 A071302 A090811 A0709 A071302 A090811	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Unable to Obtain Readings Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Unable to Obtain Readings Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Unable to Obtain Readings	 	
					CT1150	Defibrillators	E210401 F02 F10 F1203	Shock from Patient Lead(s) Death Inadequate/Inappropriate Treatment or Diagnostic Exposure Life Threatening Illness or Injury	A0709 A071302 A090811 A0709 A071302 A090811 A0709 A071302 A090811	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Unable to Obtain Readings Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Unable to Obtain Readings Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Unable to Obtain Readings	 	

								A090811	Unable to Obtain Readings		
						F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
					CT258	implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F02	Death	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F02	Death	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
					CT2806	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F02	Death	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
						F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A090811	Unable to Obtain Readings		
0060	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A070910	Undersensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	implantable defibrillators	E2104	Electric Shock	A070910	Undersensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2806	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070910	Undersensing	
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
0061	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/10/2024
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2024	17/10/2024
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/10/2024	17/10/2024
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2024	17/10/2024
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/10/2024	17/10/2024
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2024	17/10/2024
0062	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
						F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
						F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
						F26	No Health Consequences or Impact	A0705	Battery Problem		
0063	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/11/2023
								A070504	Premature Discharge of Battery	01/11/2023	01/11/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/11/2023	01/11/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/11/2023	01/11/2023
								A070504	Premature Discharge of Battery	01/11/2023	01/11/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/11/2023	01/11/2023
						F1905	Device Revision or Replacement	A0705	Battery Problem	01/11/2023	01/11/2023
								A070504	Premature Discharge of Battery	01/11/2023	01/11/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/11/2023	01/11/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/11/2023
								A070504	Premature Discharge of Battery	01/11/2023	01/11/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/11/2023	01/11/2023
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/11/2023	01/11/2023
								A070504	Premature Discharge of Battery	01/11/2023	01/11/2023
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/11/2023	01/11/2023
						F1905	Device Revision or Replacement	A0705	Battery Problem	01/11/2023	01/11/2023

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				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
CT145	Cardiovascular devices	E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
CT233	Surgical	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
				A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
CT2406	Implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
				A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
CT2407	Active implantable	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
				A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
				A0709	Device Sensing Problem	23/04/2024	23/04/2024
				A070909	Overensing	23/04/2024	23/04/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024

C12726	Physiological monitoring/measuring devices	F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
				A0709	Device Sensing Problem	23/04/2024	23/04/2024		
		F1903	Device Explanation	A070909	Overensing	23/04/2024	23/04/2024		
				A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024				
		A070909	Overensing	23/04/2024	23/04/2024				
		A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024				
F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024				
		A070909	Overensing	23/04/2024	23/04/2024				
		A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024				
C12727	Active implant devices/ancillaries	E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		C12750	Implantable cardiac electrical stimulators and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024
						A070909	Overensing	23/04/2024	23/04/2024
						A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024
F08	Hospitalization or Prolonged Hospitalization			A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
F10	Inadequate/inappropriate Treatment or Diagnostic Exposure			A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
F1903	Device Explanation			A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
F2203	Imaging Required			A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
C12866	Implantable cardiac electrical stimulators			E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024
						A070909	Overensing	23/04/2024	23/04/2024
						A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024
		F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
		C12985	Active	E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024
						A070909	Overensing	23/04/2024	23/04/2024
						A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024
F08	Hospitalization or Prolonged Hospitalization			A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
F10	Inadequate/inappropriate Treatment or Diagnostic Exposure			A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
F1903	Device Explanation			A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
F2203	Imaging Required			A0709	Device Sensing Problem	23/04/2024	23/04/2024		
				A070909	Overensing	23/04/2024	23/04/2024		
				A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024		
C13001	Implantable metal			E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024
						A070909	Overensing	23/04/2024	23/04/2024
						A071302	Inappropriate/inadequate Shock/Stimulation	23/04/2024	23/04/2024

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								F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
								F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
								F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
						C1981	Single use	E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
								F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
								F1903	Device Explanation	A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
								F2203	Imaging Required	A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing Problem	23/04/2024	23/04/2024
										A070909	Oversensing	23/04/2024	23/04/2024
										A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
										A0709	Device Sensing		

		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
		F26	No Health Consequences or Impact	A070909	Oversensing		
				A090801	Signal Artifact/Noise		
				A1301	Failure to Read Input Signal		
CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
				A090801	Signal Artifact/Noise		

						F26	No Health Consequences or Impact	A1301 A070909 A090801 A1301	Failure to Read Input Signal Oversensing Signal Artifact/Noise Failure to Read Input Signal			
				CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal			
				CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal			
				CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal			
						F26	No Health Consequences or Impact	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal			
6071	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
						F1901	Additional Surgery	A0705	Battery Problem			
						F2301	Additional Device Required	A0705	Battery Problem			
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
						F1901	Additional Surgery	A0705	Battery Problem			
						F2301	Additional Device Required	A0705	Battery Problem			
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
						F1901	Additional Surgery	A0705	Battery Problem			
						F2301	Additional Device Required	A0705	Battery Problem			
				CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
						F1901	Additional Surgery	A0705	Battery Problem			
						F2301	Additional Device Required	A0705	Battery Problem			
6072	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09 A090811	Output Problem Unable to Obtain Readings		
						F26	No Health Consequences or Impact	A09 A090811	Output Problem Unable to Obtain Readings			
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09 A090811	Output Problem Unable to Obtain Readings			
						F26	No Health Consequences or Impact	A09 A090811	Output Problem Unable to Obtain Readings			
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A09 A090811	Output Problem Unable to Obtain Readings			
						F26	No Health Consequences or Impact	A09 A090811	Output Problem Unable to Obtain Readings			
6073	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery			
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery			
						F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery			
				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery			
						F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery			
				CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery			
						F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery			
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery			
						F26	No Health Consequences or Impact	A0705 A070504	Battery Problem Premature Discharge of Battery			
6074	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504	Battery Problem Premature Discharge of Battery	01/08/2024	01/08/2024
						F08	Hospitalization or Prolonged Hospitalization	A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	01/08/2024	01/08/2024	01/08/2024
						F1903	Device Expantation	A0908 A0705 A070504	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery	01/08/2024	01/08/2024	01/08/2024
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/08/2024		01/08/2024
6075	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
				CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise			

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
8079	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
							F1903	Device Explanation	A0908	Premature Discharge of Battery	22/02/2024	22/02/2024
							F1905	Device Revision or Replacement	A070504	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
									A0908	Premature Discharge of Battery	22/02/2024	22/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
									A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
									A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
							F1903	Device Explanation	A070504	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
							F1905	Device Revision or Replacement	A0908	Premature Discharge of Battery	22/02/2024	22/02/2024
									A070504	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
									A0908	Premature Discharge of Battery	22/02/2024	22/02/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
									A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
8080	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
									A070909	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
									A0709	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A070909	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8081	2024		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
8082	2024	All other reportable incidents			CT258	implantable defibrillators	F23	Unexpected Medical Intervention	A070101	Failure to Capture		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8083	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT1147	Defibrillators and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023

					CT263	Cardiographs and associated devices	E1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT2726	Physiological monitoring/measuring devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/10/2023	12/10/2023
8084	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	10/11/2023	10/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate	10/11/2023	10/11/2023
							F12	Serious Injury/Illness/Impaired	A071102	Failure to Interrogate	10/11/2023	10/11/2023
							F1905	Device Revision or Replacement	A071102	Failure to Interrogate	10/11/2023	10/11/2023
							F26	No Health Consequences or Impact	A071102	Failure to Interrogate	10/11/2023	10/11/2023
8085	2024		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F1903	Device Explanation	A0705	Battery Problem		
8086	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/03/2024	08/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	08/03/2024	08/03/2024
									A070504	Premature Discharge of Battery	08/03/2024	08/03/2024
8087	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Improper Result or Readings		
									A1107	Data Problem		
									A13	Communication or Transmission Problem		
						F26	No Health Consequences or Impact		A0908	Incorrect, Inadequate or Improper Result or Readings		
									A1107	Data Problem		
									A13	Communication or Transmission Problem		

					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
							F26	No Health Consequences or Impact	A13	Communication or Transmission Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A13	Communication or Transmission Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
									A13	Communication or Transmission Problem		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
									A13	Communication or Transmission Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
							F26	No Health Consequences or Impact	A13	Communication or Transmission Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
									A13	Communication or Transmission Problem		
6088	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
6089	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A1301	Failure to Read Input Signal		
6090	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	04/07/2023	04/07/2023
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	04/07/2023	04/07/2023
							F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	04/07/2023	04/07/2023
6091	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
6092	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6093	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
									A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
							F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
									A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
									A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
							F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
									A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
									A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
							F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
									A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/09/2023	06/09/2023

							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
							F1903	Device Explanation	A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
									A070504	Premature Discharge of Battery	06/09/2023	06/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/09/2023	06/09/2023
6094	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/08/2023	28/08/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2023	28/08/2023
6095	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
									A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
									A1601	Device Alarm System		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
									A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
									A1601	Device Alarm System		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
									A1601	Device Alarm System		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
									A1601	Device Alarm System		
6096	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/09/2025	18/09/2025
									A072201	High Impedance	18/09/2025	18/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/09/2025	18/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/09/2025	18/09/2025
									A072201	High Impedance	18/09/2025	18/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/09/2025	18/09/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2025	18/09/2025
									A072201	High Impedance	18/09/2025	18/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/09/2025	18/09/2025
6097	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E060109	Tachycardia	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT263	Cardiographs and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		

6100	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem																	
						F26	No Health Consequences or Impact	A0705	Battery Problem																		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem																	
						F26	No Health Consequences or Impact	A0705	Battery Problem																		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System																	
						F26	No Health Consequences or Impact	A1601	Device Alarm System																		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System																	
						F26	No Health Consequences or Impact	A1601	Device Alarm System																		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System																	
						F26	No Health Consequences or Impact	A1601	Device Alarm System																		
6101	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1601	Device Alarm System																	
						F26	No Health Consequences or Impact	A1601	Device Alarm System																		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A090813	Imprecise or Erratic Results																	
						F27	Problem Identified During Non-Clinical Procedure	A090813	Imprecise or Erratic Results																		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090813	Imprecise or Erratic Results																	
						F27	Problem Identified During Non-Clinical Procedure	A090813	Imprecise or Erratic Results																		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090813	Imprecise or Erratic Results																	
						F27	Problem Identified During Non-Clinical Procedure	A090813	Imprecise or Erratic Results																		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090813	Imprecise or Erratic Results																	
						F27	Problem Identified During Non-Clinical Procedure	A090813	Imprecise or Erratic Results																		
6102	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Device Sensing Problem																	
							A070909	Oversensing																			
							A070910	Undersensing																			
							A0712	Pacing Problem																			
							A0722	Impedance Problem																			
							A1301	Failure to Read Input Signal																			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem																		
							A070909	Oversensing																			
							A070910	Undersensing																			
							A0712	Pacing Problem																			
6103	2024	All other reportable incidents		CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0708	Oversensing																		
									A070809	Signal Artifact/Noise																	
									A090801	Signal Artifact/Noise																	
									A1301	Failure to Read Input Signal																	
									F26	No Health Consequences or Impact	A070909	Oversensing															
										A090801	Signal Artifact/Noise																
										A1301	Failure to Read Input Signal																
										A070909	Oversensing																
										A090801	Signal Artifact/Noise																
										A1301	Failure to Read Input Signal																
6104	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/11/2023	22/11/2023															
										A070504	Premature Discharge of Battery	22/11/2023	22/11/2023														
										F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/11/2023	22/11/2023												
										F1903	Device Explanation	A070504	Premature Discharge of Battery	22/11/2023	22/11/2023												
										F1905	Device Revision or Replacement	A0705	Battery Problem	22/11/2023	22/11/2023												
										F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/11/2023	22/11/2023												
									CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/11/2023	22/11/2023											
														A070504	Premature Discharge of Battery	22/11/2023	22/11/2023										
														F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/11/2023	22/11/2023								
														F1903	Device Explanation	A070504	Premature Discharge of Battery	22/11/2023	22/11/2023								
						F1905	Device Revision or Replacement	A0705					Battery Problem	22/11/2023	22/11/2023												
						F1905	Device Revision or Replacement	A070504					Premature Discharge of Battery	22/11/2023	22/11/2023												
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions					A0705	Battery Problem	22/11/2023	22/11/2023											
														A070504	Premature Discharge of Battery	22/11/2023	22/11/2023										
														F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/11/2023	22/11/2023								
														F1903	Device Explanation	A070504	Premature Discharge of Battery	22/11/2023	22/11/2023								
										F1905	Device Revision or Replacement	A0705	Battery Problem	22/11/2023	22/11/2023												
										F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/11/2023	22/11/2023												
									CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	22/11/2023	22/11/2023											
														A070504	Premature Discharge of Battery	22/11/2023	22/11/2023										
														F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/11/2023	22/11/2023								
														F1903	Device Explanation	A070504	Premature Discharge of Battery	22/11/2023	22/11/2023								
						F1905	Device Revision or Replacement	A0705					Battery Problem	22/11/2023	22/11/2023												
						F1905	Device Revision or Replacement	A070504					Premature Discharge of Battery	22/11/2023	22/11/2023												
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions					A0705	Battery Problem	22/11/2023	22/11/2023											
														A070504	Premature Discharge of Battery	22/11/2023	22/11/2023										
														F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	22/11/2023	22/11/2023								
														F1903	Device Explanation	A070504	Premature Discharge of Battery	22/11/2023	22/11/2023								
										F1905	Device Revision or Replacement	A0705	Battery Problem	22/11/2023	22/11/2023												
										F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/11/2023	22/11/2023												
									6105	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023						
																			F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023			
																			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023			
																		CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023		
						F08	Hospitalization or Prolonged Hospitalization	A070504														Premature Discharge of Battery	20/10/2023	20/10/2023			
						F1905	Device Revision or Replacement	A070504														Premature Discharge of Battery	20/10/2023	20/10/2023			
						F1905	Device Revision or Replacement	A070504														Premature Discharge of Battery	20/10/2023	20/10/2023			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions														A070504	Premature Discharge of Battery	20/10/2023	20/10/2023		

6106	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
					CT2866	Implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/10/2023	20/10/2023
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
6107	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
6107	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
6108	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT1141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT1145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
6108	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2023	12/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/12/2023	12/12/2023

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								F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	23/02/2024	23/02/2024
										A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1905	Device Revision or Replacement	A072201	High Impedance	23/02/2024	23/02/2024
										A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
8111	2024	All other reportable incidents				CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A072201	High Impedance	23/02/2024	23/02/2024
										A070504	Premature Discharge of Battery		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070504	Premature Discharge of Battery		
8112	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
8113	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1150	Defibrillators	E060109	Tachycardia	A070504	Premature Discharge of Battery		
								F2303	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
						CT1258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
						CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
8114	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8115	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1901	Additional Surgery	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1903	Device Explanation	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
8116	2024	All other reportable incidents				CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/02/2024	23/02/2024
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8117	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem	08/12/2023	08/12/2023
										A090407	Therapy Delivered to Incorrect Body Area	08/12/2023	08/12/2023
										A1107	Data Problem	08/12/2023	08/12/2023
								F1901	Additional Surgery	A0722	Impedance Problem	08/12/2023	08/12/2023
										A090407	Therapy Delivered to Incorrect Body Area	08/12/2023	08/12/2023
										A1107	Data Problem	08/12/2023	08/12/2023
8118	2024		37265	Dual-chamber implantable defibrillator		CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

								F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F1903	Device Explanation	A070504	Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F1903	Device Explanation	A070504	Premature Discharge of Battery			
8119	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A071201	Failure to Convert Rhythm			
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm			
8120	2024	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2401	Insufficient Information	A27	Appropriate Device Problem Term/Code not Available			
							F02	Death	A27	Appropriate Device Problem Term/Code not Available			
8121	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator	29/02/2024	29/02/2024	
							F1903	Device Explanation	A180601	Premature Elective Replacement Indicator	29/02/2024	29/02/2024	
8122	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
8123	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
									A070910	Undersensing			
									A072201	High Impedance			
							F26	No Health Consequences or Impact	A070909	Oversensing			
									A070910	Undersensing			
									A072201	High Impedance			
8124	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/05/2023	01/05/2023	
									A070504	Premature Discharge of Battery	01/05/2023	01/05/2023	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/05/2023	01/05/2023	
									A070504	Premature Discharge of Battery	01/05/2023	01/05/2023	
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/05/2023	01/05/2023	
									A070504	Premature Discharge of Battery	01/05/2023	01/05/2023	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/05/2023	01/05/2023	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/05/2023	01/05/2023	
									A0705	Battery Problem	01/05/2023	01/05/2023	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/05/2023	01/05/2023	
									A0705	Battery Problem	01/05/2023	01/05/2023	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/05/2023	01/05/2023	
									A070504	Premature Discharge of Battery	01/05/2023	01/05/2023	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/05/2023	01/05/2023	
									A070504	Premature Discharge of Battery	01/05/2023	01/05/2023	
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/05/2023	01/05/2023	
8125	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024	
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024	
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024	
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/03/2024	18/03/2024	
									A070504	Premature Discharge of Battery	18/03/2024	18/03/2024	
8126	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings			
									A070504	Premature Discharge of Battery			
									A0908	Incorrect, Inadequate or Imprecise Result or Readings			
8127	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
					CT1150	Defibrillators	E020201	Anxiety	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
									A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F1903	Device Explanation	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
					CT258	Implantable defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	

6133	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
6134	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation	14/03/2024	14/03/2024
									A0705	Battery Problem	14/03/2024	14/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
									A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	14/03/2024	14/03/2024
					CT1150	Defibrillators			A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	14/03/2024	14/03/2024
					CT258	Implantable defibrillators			A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	14/03/2024	14/03/2024
					CT263	Cardiographs and associated devices			A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	14/03/2024	14/03/2024
					CT2866	Implantable cardiac electrical stimulators			A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/03/2024	14/03/2024
									A070504	Premature Discharge of Battery	14/03/2024	14/03/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/03/2024	14/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	14/03/2024	14/03/2024
6135	2024	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	29/02/2024	29/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	29/02/2024	29/02/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	29/02/2024	29/02/2024
6136	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6137	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F15	Recognized Device or Procedural Complication	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A040101	Fracture		
									A0709	Device Sensing Problem		
6138	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A040101	Fracture		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A090801	Signal Artifact/Noise		
									A040101	Fracture		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

6139	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A070909	Oversensing		
6140	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0722	Impedance Problem		
									A070909	Oversensing		
									A0722	Impedance Problem		
									A070909	Oversensing		
6141	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A070909	Oversensing		
6142	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
									A071201	Failure to Convert Rhythm		
									A071201	Failure to Convert Rhythm		
									A071201	Failure to Convert Rhythm		
									A071201	Failure to Convert Rhythm		
6143	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A071201	Failure to Convert Rhythm		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
6144	2024	All other reportable incidents			CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A071301	Failure to Deliver Shock/Stimulation		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization		
									A0712	Pacing Problem		
6145	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071202	Inaccurate Synchronization		
									A0508	Noise, Audible		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0508	Noise, Audible		
									A070909	Oversensing		
6146	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A072201	High Impedance		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

8147	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation						
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation						
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation						
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation						
					CT1010	Cardiovascular physiology analysis/mapping devices	F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation						
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation						
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation						
							CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation				
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A071302	Inappropriate/Inadequate Shock/Stimulation						
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation						
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation													
CT1263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302			Inappropriate/Inadequate Shock/Stimulation									
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302			Inappropriate/Inadequate Shock/Stimulation									
CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation											
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation											
		8148	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/09/2024	08/09/2024		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/09/2024	08/09/2024				
F08	Hospitalization or Prolonged Hospitalization								A070504	Premature Discharge of Battery	08/09/2024	08/09/2024				
A0908	Incorrect, Inadequate or Imprecise Result or Readings								08/09/2024	08/09/2024						
F1903	Device Explanation								A070504	Premature Discharge of Battery	08/09/2024	08/09/2024				
A0908	Incorrect, Inadequate or Imprecise Result or Readings								08/09/2024	08/09/2024						
CT258	Implantable defibrillators								E2401	Insufficient Information	A0705	Battery Problem				
									F23	Unexpected Medical Intervention	A0705	Battery Problem				
									CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
											F26	No Health Consequences or Impact	A2304	Off-Label Use		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance											
		F26	No Health Consequences or Impact	A2304	Off-Label Use											
		CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance									
				F26	No Health Consequences or Impact	A2304	Off-Label Use									
CT1263	Cardiographs and associated devices			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance									
				F26	No Health Consequences or Impact	A2304	Off-Label Use									
		CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance									
				F26	No Health Consequences or Impact	A2304	Off-Label Use									
8151	2024			All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break				
									A150201	Positioning Failure						
		F1908	Prolonged Surgery						A23	Use of Device Problem						
		A0401	Break													
		A150201	Positioning Failure													
		A23	Use of Device Problem													
		CT258	Implantable defibrillators				E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break						
							A150201	Positioning Failure								
							F1908	Prolonged Surgery	A0401	Break						
							A150201	Positioning Failure								
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break											
		A150201	Positioning Failure													
		F1908	Prolonged Surgery	A23	Use of Device Problem											
		A0401	Break													
		A150201	Positioning Failure													
		A23	Use of Device Problem													
8152	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem						
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal						
							F26	No Health Consequences or Impact	A0722	Impedance Problem						
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal						
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance						
							F26	No Health Consequences or Impact	A072201	High Impedance						
							CT1150	Defibrillators	E011903	Syncope/Fainting	A070909	Oversensing				
									A071201	Failure to Convert Rhythm						
									E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation				
									A070909	Oversensing						
8153	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance						
							F26	No Health Consequences or Impact	A072201	High Impedance						
							CT1150	Defibrillators	E011903	Syncope/Fainting	A070909	Oversensing				
									A071201	Failure to Convert Rhythm						
					E210401	Shock from Patient Lead(s)			A071302	Inappropriate/Inadequate Shock/Stimulation						
					A070909	Oversensing										
					A071201	Failure to Convert Rhythm										
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A071302	Inappropriate/Inadequate Shock/Stimulation						
					CT258	Implantable defibrillators	E011903	Syncope/Fainting	A070909	Oversensing						
							A071201	Failure to Convert Rhythm								
E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation													
A070909	Oversensing															

										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
										A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting		A070909	Oversensing		
										A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)		A070909	Oversensing		
										A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
										A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
										A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
6155	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0508	Noise, Audible	25/04/2024	25/04/2024
										A070504	Premature Discharge of Battery	25/04/2024	25/04/2024
							F08	Hospitalization or Prolonged Hospitalization		A0508	Noise, Audible	25/04/2024	25/04/2024
										A070504	Premature Discharge of Battery	25/04/2024	25/04/2024
							F1905	Device Revision or Replacement		A0508	Noise, Audible	25/04/2024	25/04/2024
										A070504	Premature Discharge of Battery	25/04/2024	25/04/2024
6156	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060102	Atrial Fibrillation		A0712	Pacing Problem		
							F12	Serious Injury/Illness/ Impairment		A0712	Pacing Problem		
							F23	Unexpected Medical Intervention		A0712	Pacing Problem		
					CT1150	Defibrillators	E060102	Atrial Fibrillation		A0712	Pacing Problem		
							F12	Serious Injury/Illness/ Impairment		A0712	Pacing Problem		
							F23	Unexpected Medical Intervention		A0712	Pacing Problem		
					CT258	Implantable defibrillators	E060102	Atrial Fibrillation		A0712	Pacing Problem		
							F12	Serious Injury/Illness/ Impairment		A0712	Pacing Problem		
							F23	Unexpected Medical Intervention		A0712	Pacing Problem		
					CT263	Cardiographs and associated devices	E060102	Atrial Fibrillation		A0712	Pacing Problem		
							F12	Serious Injury/Illness/ Impairment		A0712	Pacing Problem		
							F23	Unexpected Medical Intervention		A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060102	Atrial Fibrillation		A0712	Pacing Problem		
							F12	Serious Injury/Illness/ Impairment		A0712	Pacing Problem		
							F23	Unexpected Medical Intervention		A0712	Pacing Problem		
6157	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation		A160602	Premature End-of-Life Indicator		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation		A160602	Premature End-of-Life Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A160602	Premature End-of-Life Indicator		
							F1903	Device Explanation		A160602	Premature End-of-Life Indicator		
6158	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance		
							F26	No Health Consequences or Impact		A072201	High Impedance		
6159	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A1107	Data Problem		
							F26	No Health Consequences or Impact		A1107	Data Problem		
6160	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance		
							F26	No Health Consequences or Impact		A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance		
							F26	No Health Consequences or Impact		A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance		
							F26	No Health Consequences or Impact		A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance		
							F26	No Health Consequences or Impact		A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance		
							F26	No Health Consequences or Impact		A072201	High Impedance		
6161	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060101	Asystole		A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment		A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E060101	Asystole		A070909	Oversensing		
										A0712	Pacing Problem		
							F1001	Absence of Treatment		A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E060101	Asystole		A070909	Oversensing		
										A0712	Pacing Problem		
										A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment		A070909	Oversensing		
										A0712	Pacing Problem		
6162	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
6163	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E011903	Syncope/Fainting		A0713	Defibrillation/Stimulation Problem		
							E060110	Ventricular Fibrillation		A0713	Defibrillation/Stimulation Problem		
							E2007	Fall		A0713	Defibrillation/Stimulation Problem		
							F08	Hospitalization or Prolonged Hospitalization		A0713	Defibrillation/Stimulation Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury		A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device		A0713	Defibrillation/Stimulation Problem		
					CT1150	Defibrillators	E011903	Syncope/Fainting		A0713	Defibrillation/Stimulation Problem		

							E060110	Ventricular Fibrillation	A0713	Defibrillation/Stimulation Problem		
							E2007	Fall	A0713	Defibrillation/Stimulation Problem		
							F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
						C1258	E011903	Syncope/Fainting	A0713	Defibrillation/Stimulation Problem		
							E060110	Ventricular Fibrillation	A0713	Defibrillation/Stimulation Problem		
							E2007	Fall	A0713	Defibrillation/Stimulation Problem		
							F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
						C1263	E011903	Syncope/Fainting	A0713	Defibrillation/Stimulation Problem		
							E060110	Ventricular Fibrillation	A0713	Defibrillation/Stimulation Problem		
							E2007	Fall	A0713	Defibrillation/Stimulation Problem		
							F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
						C12866	E011903	Syncope/Fainting	A0713	Defibrillation/Stimulation Problem		
							E060110	Ventricular Fibrillation	A0713	Defibrillation/Stimulation Problem		
							E2007	Fall	A0713	Defibrillation/Stimulation Problem		
							F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0713	Defibrillation/Stimulation Problem		
8164	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	C11150	Defibrillators	F1203	Life Threatening Illness or Injury	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2024	21/03/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/03/2024	21/03/2024
					C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2024	21/03/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/03/2024	21/03/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/03/2024	21/03/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	21/03/2024	21/03/2024
8165	2024	All other reportable incidents			C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
8166	2024	All other reportable incidents			C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8167	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8168	2024		37265	Dual-chamber implantable defibrillator	C11150	Defibrillators	E0601	Arrhythmia	A07	Clinical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A07	Electrical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
					C1258	Implantable defibrillators	E0601	Arrhythmia	A07	Clinical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
					C12866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A07	Clinical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A071201	Failure to Convert Rhythm		
8169	2024	All other reportable incidents			C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/06/2024	11/06/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/06/2024	11/06/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	11/06/2024	11/06/2024
							E210401	Shock from Patient Lead(s)	A070909	Oversensing		
8170	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	C1258	Implantable defibrillators			A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Undersensing		
									A070910	Undersensing		
							F17	Sedation	A070909	Oversensing		
									A070910	Undersensing		
							F2203	Imaging Required	A070909	Oversensing		
8171	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
							E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
					C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
					C1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
					C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
8172	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
							F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available		
							F2303	Medication Required	A27	Appropriate Device Problem Term/Code not Available		
							E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
					CT1150	Defibrillators	F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available		
									A27	Appropriate Device Problem Term/Code not Available		
									A27	Appropriate Device Problem Term/Code not Available		
									A27	Appropriate Device Problem Term/Code not Available		

					CT258	Implantable defibrillators	E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
							F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available		
							F2303	Medication Required	A27	Appropriate Device Problem Term/Code not Available		
					CT263	Cardiographs and associated devices	E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
							F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available		
							F2303	Medication Required	A27	Appropriate Device Problem Term/Code not Available		
					CT2866	Implantable cardiac electrical stimulators	E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
							F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available		
							F2303	Medication Required	A27	Appropriate Device Problem Term/Code not Available		
6173	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0705	Battery Problem		
									A070602	Delayed Charge Time		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6174	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0405	Degraded		
							F27	Problem Identified During Non-Clinical Procedure	A0405	Degraded		
6175	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F27	Problem Identified During Non-Clinical Procedure	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
6176	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A0508	Noise, Audible		
									A070909	Oversensing		
									A070910	Undersensing		
									A0713	Defibrillation/Stimulation Problem		
						E0623	Unspecified Heart Problem		A0508	Noise, Audible		
									A070909	Oversensing		
									A070910	Undersensing		
									A0713	Defibrillation/Stimulation Problem		
						F08	Hospitalization or Prolonged Hospitalization		A0508	Noise, Audible		
									A070909	Oversensing		
									A070910	Undersensing		
									A0713	Defibrillation/Stimulation Problem		
						F15	Recognized Device or Procedural Complication		A0508	Noise, Audible		
									A070909	Oversensing		
									A070910	Undersensing		
									A0713	Defibrillation/Stimulation Problem		
						F2303	Medication Required		A0508	Noise, Audible		
									A070909	Oversensing		
									A070910	Undersensing		
									A0713	Defibrillation/Stimulation Problem		
					CT1150	Defibrillators	E060109	Tachycardia	A0508	Noise, Audible		
									A070909	Oversensing		
									A070910	Undersensing		
									A0713	Defibrillation/Stimulation Problem		
						E0623	Unspecified Heart Problem		A0508	Noise, Audible		
									A070909	Oversensing		
									A070910	Undersensing		
									A0713	Defibrillation/Stimulation Problem		

						F08	Hospitalization or Prolonged Hospitalization	A0713 A0508 A070909 A070910 A0713	Defibrillation/Stimulation Problem Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						F15	Recognized Device or Procedural Complication	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						P2303	Medication Required	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
				CT258	Implantable defibrillators	E060109	Tachycardia	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						E0623	Unspecified Heart Problem	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						F08	Hospitalization or Prolonged Hospitalization	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						F15	Recognized Device or Procedural Complication	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						P2303	Medication Required	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
				CT263	Cardiographs and associated devices	E060109	Tachycardia	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						E0623	Unspecified Heart Problem	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						F08	Hospitalization or Prolonged Hospitalization	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						F15	Recognized Device or Procedural Complication	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						P2303	Medication Required	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
				CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						E0623	Unspecified Heart Problem	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						F08	Hospitalization or Prolonged Hospitalization	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						F15	Recognized Device or Procedural Complication	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
						P2303	Medication Required	A0508 A070909 A070910 A0713	Noise, Audible Oversensing Undersensing Defibrillation/Stimulation Problem			
6177	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping device	E2403 P10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem		
					CT1150	Defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem		
					CT258	Implantable defibrillators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem		
					CT263	Cardiographs and associated devices	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A0712	Pacing Problem Pacing Problem		
6178	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A071204	Oversensing No Pacing		

							F22	Unexpected Diagnostic Intervention	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071204	No Pacing		
									A070909	Oversensing		
							F22	Unexpected Diagnostic Intervention	A071204	No Pacing		
									A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071204	No Pacing		
									A070909	Oversensing		
							F22	Unexpected Diagnostic Intervention	A071204	No Pacing		
									A070909	Oversensing		
									A071204	No Pacing		
8179	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
8180	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/09/2023	27/09/2023
									A070504	Premature Discharge of Battery	27/09/2023	27/09/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/09/2023	27/09/2023
							F24	Insufficient Health Impact Information	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F24	Insufficient Health Impact Information	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8181	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0112	Dizziness	A070909	Oversensing		
									A0712	Pacing Problem		
							E060104	Bradycardia	A070909	Oversensing		
									A0712	Pacing Problem		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F2203	Imaging Required	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT258	implantable defibrillators	E0112	Dizziness	A070909	Oversensing		
							E060104	Bradycardia	A0712	Pacing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A0712	Pacing Problem		
									A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E0112	Dizziness	A0712	Pacing Problem		
							E060104	Bradycardia	A070909	Oversensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F2203	Imaging Required	A0712	Pacing Problem		
									A070909	Oversensing		
8182	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/05/2024	23/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2024	23/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/05/2024	23/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2024	23/05/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/05/2024	23/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/05/2024	23/05/2024
8183	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/01/2025	29/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/01/2025	29/01/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/01/2025	29/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/01/2025	29/01/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/01/2025	29/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/01/2025	29/01/2025
8184	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/05/2024	20/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/05/2024	20/05/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/05/2024	20/05/2024
8185	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/Illness/ Impairment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8186	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2311	Discomfort	A010402	Migration		
							F26	No Health Consequences or Impact	A010402	Migration		
8187	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8188	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8189	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8190	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0901	Audible Prompt/Feedback Problem		
							F27	Problem Identified During Non-Clinical Procedure	A0901	Audible Prompt/Feedback Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0901	Audible Prompt/Feedback Problem		
							F27	Problem Identified During Non-Clinical Procedure	A0901	Audible Prompt/Feedback Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0901	Audible Prompt/Feedback Problem		
							F27	Problem Identified During Non-Clinical Procedure	A0901	Audible Prompt/Feedback Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0901	Audible Prompt/Feedback Problem		
							F27	Problem Identified During Non-Clinical Procedure	A0901	Audible Prompt/Feedback Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0901	Audible Prompt/Feedback Problem		
							F27	Problem Identified During Non-Clinical Procedure	A0901	Audible Prompt/Feedback Problem		
8191	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0514	Thrombosis/Thrombus	A24	No Apparent Device Problem		
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem		
					CT1150	Defibrillators	E0514	Thrombosis/Thrombus	A24	No Apparent Device Problem		
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem		
					CT258	Implantable defibrillators	E0514	Thrombosis/Thrombus	A24	No Apparent Device Problem		
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem		
					CT263	Cardiographs and associated devices	E0514	Thrombosis/Thrombus	A24	No Apparent Device Problem		
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem		
					CT2866	Implantable cardiac electrical stimulators	E0514	Thrombosis/Thrombus	A24	No Apparent Device Problem		
							F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem		
8192	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2024	12/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/06/2024	12/06/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2024	12/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/06/2024	12/06/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	12/06/2024	12/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/06/2024	12/06/2024
8193	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/Illness/ Impairment	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
8194	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025

							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
									A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
6195	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
6196	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/06/2024	19/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/06/2024	19/06/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/06/2024	19/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/06/2024	19/06/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/06/2024	19/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/06/2024	19/06/2024
6197	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
6198	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A072201	High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A072201	High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A072201	High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A072201	High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A072201	High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A072201	High Impedance		
6199	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
6200	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem	23/04/2024	23/04/2024
									A070909	Over-sensing	23/04/2024	23/04/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	23/04/2024	23/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	23/04/2024	23/04/2024

8203	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	03/05/2024	03/05/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		03/05/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/05/2024	03/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/05/2024	03/05/2024
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	03/05/2024	03/05/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/05/2024	03/05/2024
					CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8204	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
8205	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem		
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
8206	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8207	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0112	Dizziness	A0709	Device Sensing Problem		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2310	Diaphoresis	A0709	Device Sensing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E0112	Dizziness	A0709	Device Sensing Problem		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2310	Diaphoresis	A0709	Device Sensing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E0112	Dizziness	A0709	Device Sensing Problem		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2310	Diaphoresis	A0709	Device Sensing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0112	Dizziness	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							E2310	Diaphoresis	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
8208	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8209	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2024	07/05/2024
							F1901	Additional Surgery	A071102	Failure to Interrogate	07/05/2024	07/05/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2024	07/05/2024
							F1901	Additional Surgery	A070504	Failure to Interrogate	07/05/2024	07/05/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	07/05/2024	07/05/2024
							F1901	Additional Surgery	A071102	Failure to Interrogate	07/05/2024	07/05/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2024	07/05/2024
							F1901	Additional Surgery	A071102	Failure to Interrogate	07/05/2024	07/05/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2024	07/05/2024
							F1901	Additional Surgery	A071102	Failure to Interrogate	07/05/2024	07/05/2024
8210	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	07/05/2024	07/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		

					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8211	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
8212	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E011903	Syncope/Fainting	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT1150	Defibrillators	E011903	Syncope/Fainting	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	E011903	Syncope/Fainting	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT263	Cardiographs and associated devices	E011903	Syncope/Fainting	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
8213	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Electromagnetic Interference		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		

							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
8214	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8215	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0119	Loss of Consciousness	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E011903	Syncope/Fainting	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E0601	Arrhythmia	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E0119	Loss of Consciousness	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E011903	Syncope/Fainting	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E0119	Loss of Consciousness	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E011903	Syncope/Fainting	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E0119	Loss of Consciousness	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E011903	Syncope/Fainting	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT266	Implantable cardiac electrical stimulators	E0119	Loss of Consciousness	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E011903	Syncope/Fainting	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

6216	2024	All other reportable incidents			C1258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071202 A071302	Pacing Problem Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A0712 A071202	Pacing Problem Inaccurate Synchronization		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302 A070909 A070910 A1301	Inappropriate/Inadequate Shock/Stimulation Oversensing Undersensing Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910	Oversensing Undersensing		
							E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F24	Insufficient Health Impact Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F24	Insufficient Health Impact Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
6217	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	C11150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F24	Insufficient Health Impact Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F24	Insufficient Health Impact Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E2401	Insufficient Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F24	Insufficient Health Impact Information	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
6218	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	C11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001	Oversensing Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A070909 A072001	Oversensing Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909 A072001	Oversensing Electromagnetic Interference		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001	Oversensing Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A070909 A072001	Oversensing Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909 A072001	Oversensing Electromagnetic Interference		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001	Oversensing Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A070909 A072001	Oversensing Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909 A072001	Oversensing Electromagnetic Interference		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001	Oversensing Electromagnetic Interference		
6219	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	C11010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							E210401	Shock from Patient Lead(s)	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
6219	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	C11150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							E210401	Shock from Patient Lead(s)	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
6219	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	C1258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							E210401	Shock from Patient Lead(s)	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
6219	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	C1263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							E210401	Shock from Patient Lead(s)	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/Inadequate Shock/Stimulation Reset Problem	10/05/2024	10/05/2024
6219	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	C12866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	10/05/2024	10/05/2024

							F08	Hospitalization or Prolonged Hospitalization	A1605 A071302	Reset Problem Inappropriate/inadequate Shock/Stimulation	10/05/2024 10/05/2024	10/05/2024 10/05/2024
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A071302 A1605	Inappropriate/inadequate Shock/Stimulation Reset Problem	10/05/2024 10/05/2024	10/05/2024 10/05/2024
							F1203	Life Threatening Illness or Injury	A071302 A1605	Inappropriate/inadequate Shock/Stimulation Reset Problem	10/05/2024 10/05/2024	10/05/2024 10/05/2024
							F1903	Device Explanation	A071302 A1605	Inappropriate/inadequate Shock/Stimulation Reset Problem	10/05/2024 10/05/2024	10/05/2024 10/05/2024
6220	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
6221	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E0138	Undesired Nerve Stimulation	A0723	Unexpected Mode Switch	17/10/2023	17/10/2023
							F1905	Device Revision or Replacement	A0723	Unexpected Mode Switch	17/10/2023	17/10/2023
6222	2024	All other reportable incidents	57265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302 A0709	Inappropriate/inadequate Shock/Stimulation Device Sensing Problem		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709 A071302	Device Sensing Problem Inappropriate/inadequate Shock/Stimulation		
6223	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302 A070504	Inappropriate/inadequate Shock/Stimulation Premature Discharge of Battery	14/05/2024	14/05/2024
							F1901	Failure to Interrogate	A071102	Failure to Interrogate	14/05/2024	14/05/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2024	14/05/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	14/05/2024	14/05/2024
							F1901	Premature Discharge of Battery	A070504	Premature Discharge of Battery	14/05/2024	14/05/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	14/05/2024	14/05/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	14/05/2024	14/05/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	14/05/2024	14/05/2024
							F1901	Failure to Interrogate	A071102	Failure to Interrogate	14/05/2024	14/05/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	Premature Discharge of Battery	A070504	Premature Discharge of Battery	14/05/2024	14/05/2024
							F1901	Failure to Interrogate	A071102	Failure to Interrogate	14/05/2024	14/05/2024
							F1901	Premature Discharge of Battery	A070504	Premature Discharge of Battery	14/05/2024	14/05/2024
6224	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate	14/05/2024	14/05/2024
							F26	Failure to Capture	A070101	Impedance Problem		
								No Health Consequences or Impact	A070101	Device Sensing Problem		
									A0722	Impedance Problem		
6225	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/Illness/Impairment	A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F12	Serious Injury/Illness/Impairment	A070909	Oversensing		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/Illness/Impairment	A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F12	Serious Injury/Illness/Impairment	A070909	Oversensing		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		

							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
8226	2024	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E060110	Ventricular Fibrillation	A071301	Failure to Deliver Shock/Stimulation		
							F02	Death	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT263	Cardiographs and associated devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
8227	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
									A070912	Incorrect Interpretation of Signal		
									A071301	Failure to Deliver Shock/Stimulation		
					CT1150	Defibrillators	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
									A070912	Incorrect Interpretation of Signal		
									A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
									A070912	Incorrect Interpretation of Signal		
									A071301	Failure to Deliver Shock/Stimulation		
					CT263	Cardiographs and associated devices	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Stimulation		
									A070912	Incorrect Interpretation of Signal		
									A071301	Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
							F23	Unexpected Medical Intervention	A070912	Incorrect Interpretation of Signal		
									A071301	Failure to Deliver Shock/Stimulation		
8228	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
					CT1150	Defibrillators	E0601	Arrhythmia	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A0712	Pacing Problem		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A0712	Pacing Problem		
					CT263	Cardiographs and associated devices	E0601	Arrhythmia	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
8229	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A090805	Incorrect Measurement		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090805	Incorrect Measurement		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A090805	Incorrect Measurement		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090805	Incorrect Measurement		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090805	Incorrect Measurement		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090805	Incorrect Measurement		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090805	Incorrect Measurement		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A090805	Incorrect Measurement		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090805	Incorrect Measurement		
8230	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A071201	Failure to Convert Rhythm		
							E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
8231	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A072201	High Impedance		
8232	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
8233	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
8234	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
8235	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1107	Data Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1107	Data Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1107	Data Problem		
									A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
									A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1107	Data Problem		
8236	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2401	Insufficient Information	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
					CT1150	Defibrillators	E2401	Insufficient Information	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
					CT258	Implantable defibrillators	E2401	Insufficient Information	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
					CT263	Cardiographs and associated devices	E2401	Insufficient Information	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
							F1903	Device Explanation	A160602	Premature End-of-Life Indicator	15/05/2024	15/05/2024
8237	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

						CT258	Implantable defibrillators	F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
								E2307	Reprogramming of Device	A0709	Device Sensing Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
								CT263	Cardiographs and associated devices	F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem
F2307	Reprogramming of Device	A0709	Device Sensing Problem										
E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem										
F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem										
F2307	Reprogramming of Device	A0709	Device Sensing Problem										
E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem										
F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem										
F2307	Reprogramming of Device	A0709	Device Sensing Problem										
E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem										
F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem										
F2307	Reprogramming of Device	A0709	Device Sensing Problem										
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem								
F12		Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem									
F2307		Reprogramming of Device	A0709	Device Sensing Problem									
E2403		No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem									
F12		Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem									
F2307		Reprogramming of Device	A0709	Device Sensing Problem									
E2403		No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem									
F12		Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem									
F2307		Reprogramming of Device	A0709	Device Sensing Problem									
E2403		No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem									
F12		Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem									
F2307		Reprogramming of Device	A0709	Device Sensing Problem									
6238	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060110	Ventricular Fibrillation	A071202	Inaccurate Synchronization			
							F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization			
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization			
							E060110	Ventricular Fibrillation	A071202	Inaccurate Synchronization			
							F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization			
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization			
							E060110	Ventricular Fibrillation	A071202	Inaccurate Synchronization			
							F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization			
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization			
							E060110	Ventricular Fibrillation	A071202	Inaccurate Synchronization			
							F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization			
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization			
6239	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024	
						CT1150	Defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
						CT258	Implantable defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
						CT263	Cardiographs and associated devices	E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
						CT2866	Implantable cardiac electrical stimulators	E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								E020201	Anxiety	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
								F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/02/2024	22/02/2024
6240	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/02/2024	22/02/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023	
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023	
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023	
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023	
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11/2023	18/11/2023
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2023	18/11/2023
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/11	

6241	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0908	Incorrect, Inadequate or Imprecise Result or Readings	16/11/2023	16/11/2023		
									A070909	Oversensing				
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A090801	Signal Artifact/Noise				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A090801	Signal Artifact/Noise				
									A070504	Premature Discharge of Battery	26/06/2024	26/06/2024		
6242	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/06/2024	26/06/2024		
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/06/2024	26/06/2024
									F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/06/2024	26/06/2024
											A070504	Premature Discharge of Battery	26/06/2024	26/06/2024
	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/05/2024	22/05/2024		
									F08	Hospitalization or Prolonged Hospitalization	A071102	Failure to Interrogate	22/05/2024	22/05/2024
									F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	22/05/2024	22/05/2024
									F1905	Device Revision or Replacement	A071102	Failure to Interrogate	22/05/2024	22/05/2024
									A070504	Premature Discharge of Battery	22/05/2024	22/05/2024		
									A071102	Failure to Interrogate	22/05/2024	22/05/2024		
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/05/2024	22/05/2024
									F12	Serious Injury/ Illness/ Impairment	A071102	Failure to Interrogate	22/05/2024	22/05/2024
									A070504	Premature Discharge of Battery	22/05/2024	22/05/2024		
									F1905	Device Revision or Replacement	A071102	Failure to Interrogate	22/05/2024	22/05/2024
											A070504	Premature Discharge of Battery	22/05/2024	22/05/2024
											A071102	Failure to Interrogate	22/05/2024	22/05/2024
									A070504	Premature Discharge of Battery	22/05/2024	22/05/2024		
											A071102	Failure to Interrogate	22/05/2024	22/05/2024
											A070504	Premature Discharge of Battery	22/05/2024	22/05/2024
											A071102	Failure to Interrogate	22/05/2024	22/05/2024
	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
									F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
											A070909	Oversensing		
											A090801	Signal Artifact/Noise		
6245	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference				
									F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
											A072001	Electromagnetic Interference		
											A090801	Signal Artifact/Noise		
									A072001	Electromagnetic Interference				
									F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
											A072001	Electromagnetic Interference		
											A090801	Signal Artifact/Noise		
									A072001	Electromagnetic Interference				
									F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
											A072001	Electromagnetic Interference		
											A090801	Signal Artifact/Noise		
6246	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem				
											A090811	Unable to Obtain Readings		
									F26	No Health Consequences or Impact	A13	Communication or Transmission Problem		
											A09	Output Problem		
									A090811	Unable to Obtain Readings				
											A13	Communication or Transmission Problem		
											A09	Output Problem		
											A090811	Unable to Obtain Readings		
6247	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060102	Atrial Fibrillation	A24	No Apparent Device Problem				
									F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem		
									F2306	Resuscitation	A24	No Apparent Device Problem		
											A24	No Apparent Device Problem		
									E060102	Atrial Fibrillation	A24	No Apparent Device Problem		
									F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem		
									F2306	Resuscitation	A24	No Apparent Device Problem		
											A24	No Apparent Device Problem		
									E060102	Atrial Fibrillation	A24	No Apparent Device Problem		
									F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem		
									F2306	Resuscitation	A24	No Apparent Device Problem		
											A24	No Apparent Device Problem		
									E060102	Atrial Fibrillation	A24	No Apparent Device Problem		
									F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem		
									F2306	Resuscitation	A24	No Apparent Device Problem		
											A24	No Apparent Device Problem		
									E060102	Atrial Fibrillation	A24	No Apparent Device Problem		
									F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem		
									F2306	Resuscitation	A24	No Apparent Device Problem		
											A24	No Apparent Device Problem		
6248	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	19/07/2024	19/07/2024		
											A070504	Premature Discharge of Battery	19/07/2024	19/07/2024
									F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/07/2024	19/07/2024
											A0705	Battery Problem	19/07/2024	19/07/2024
									A070504	Premature Discharge of Battery	19/07/2024	19/07/2024		
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/07/2024	19/07/2024
									F1905	Device Revision or Replacement	A0705	Battery Problem	19/07/2024	19/07/2024
											A070504	Premature Discharge of Battery	19/07/2024	19/07/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/07/2024	19/07/2024		
											A070504	Premature Discharge of Battery	11/07/2024	11/07/2024
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2024	11/07/2024
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/07/2024	11/07/2024
									A070504	Premature Discharge of Battery	11/07/2024	11/07/2024		
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2024	11/07/2024
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/07/2024	11/07/2024
											A070504	Premature Discharge of Battery	11/07/2024	11/07/2024
6249	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2024	11/07/2024		
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2024	11/07/2024
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/07/2024	11/07/2024
									F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2024	11/07/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/07/2024	11/07/2024		
											A070504	Premature Discharge of Battery	11/07/2024	11/07/2024
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/07/2024	11/07/2024
											A070504	Premature Discharge of Battery	11/07/2024	11/07/2024

6250	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A072201	High Impedance															
							F17	Sedation	A072201	Incorrect, Inadequate or Imprecise Result or Readings															
									A0908	High Impedance															
							F22	Unexpected Diagnostic Intervention	A072201	Incorrect, Inadequate or Imprecise Result or Readings															
									A0908	High Impedance															
									A0908	Incorrect, Inadequate or Imprecise Result or Readings															
					CT1150	Defibrillators	E2104	Electric Shock	A072201	High Impedance															
									A0908	Incorrect, Inadequate or Imprecise Result or Readings															
							F17	Sedation	A072201	High Impedance															
									A0908	Incorrect, Inadequate or Imprecise Result or Readings															
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance															
									A0908	Incorrect, Inadequate or Imprecise Result or Readings															
		CT258	Implantable defibrillators	E2104	Electric Shock	A072201	High Impedance																		
						A0908	Incorrect, Inadequate or Imprecise Result or Readings																		
				F17	Sedation	A072201	High Impedance																		
						A0908	Incorrect, Inadequate or Imprecise Result or Readings																		
				F22	Unexpected Diagnostic Intervention	A072201	High Impedance																		
						A0908	Incorrect, Inadequate or Imprecise Result or Readings																		
		CT263	Cardiographs and associated devices	E2104	Electric Shock	A072201	High Impedance																		
						A0908	Incorrect, Inadequate or Imprecise Result or Readings																		
				F17	Sedation	A072201	High Impedance																		
						A0908	Incorrect, Inadequate or Imprecise Result or Readings																		
				F22	Unexpected Diagnostic Intervention	A072201	High Impedance																		
						A0908	Incorrect, Inadequate or Imprecise Result or Readings																		
CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A072201	High Impedance																				
				A0908	Incorrect, Inadequate or Imprecise Result or Readings																				
		F17	Sedation	A072201	High Impedance																				
				A0908	Incorrect, Inadequate or Imprecise Result or Readings																				
		F22	Unexpected Diagnostic Intervention	A072201	High Impedance																				
				A0908	Incorrect, Inadequate or Imprecise Result or Readings																				
6251	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device															
									A070909	Oversensing															
									A070910	Undersensing															
									A072202	Low Impedance															
									A090801	Signal Artifact/Noise															
									A1301	Failure to Read Input Signal															
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0203	Defective Device													
											A070909	Oversensing													
											A070910	Undersensing													
											A072202	Low Impedance													
											A090801	Signal Artifact/Noise													
											A1301	Failure to Read Input Signal													
							6252	2024			All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing						
																		A072201	High Impedance						
																		A090801	Signal Artifact/Noise						
																		A1301	Failure to Read Input Signal						
																		A070909	Oversensing						
																		A072201	High Impedance						
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure								A090801	Signal Artifact/Noise						
																		A1301	Failure to Read Input Signal						
																		A070909	Oversensing						
																		A072201	High Impedance						
																		A090801	Signal Artifact/Noise						
																		A1301	Failure to Read Input Signal						
6253	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices										E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024				
																		A071102	Failure to Interrogate	02/07/2024	02/07/2024				
																		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024		
																				A071102	Failure to Interrogate	02/07/2024	02/07/2024		
																		F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024		
																				A071102	Failure to Interrogate	02/07/2024	02/07/2024		
									F1905	Device Revision or Replacement								A070504	Premature Discharge of Battery	02/07/2024	02/07/2024				
																		A071102	Failure to Interrogate	02/07/2024	02/07/2024				
																CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024		
																						A071102	Failure to Interrogate	02/07/2024	02/07/2024
																				F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024
																						A071102	Failure to Interrogate	02/07/2024	02/07/2024
					F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024															
							A071102	Failure to Interrogate	02/07/2024	02/07/2024															
					F1905	Device Revision or Replacement			A070504	Premature Discharge of Battery	02/07/2024	02/07/2024													
									A071102	Failure to Interrogate	02/07/2024	02/07/2024													
							CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024											
													A071102	Failure to Interrogate	02/07/2024			02/07/2024							
											F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/07/2024			02/07/2024							
													A071102	Failure to Interrogate	02/07/2024			02/07/2024							
					F12	Serious Injury/ Illness/ Impairment					A070504	Premature Discharge of Battery	02/07/2024	02/07/2024											
											A071102	Failure to Interrogate	02/07/2024	02/07/2024											
					F1905	Device Revision or Replacement					A070504	Premature Discharge of Battery	02/07/2024	02/07/2024											
											A071102	Failure to Interrogate	02/07/2024	02/07/2024											
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504					Premature Discharge of Battery	02/07/2024	02/07/2024														
										A071102	Failure to Interrogate	02/07/2024	02/07/2024												
				F08					Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024												
										A071102	Failure to Interrogate	02/07/2024	02/07/2024												
				F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024																
						A071102	Failure to Interrogate	02/07/2024	02/07/2024																
		F1905	Device Revision or Replacement			A070504	Premature Discharge of Battery	02/07/2024	02/07/2024																
						A071102	Failure to Interrogate	02/07/2024	02/07/2024																
				CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024														
										A071102	Failure to Interrogate	02/07/2024	02/07/2024												
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	02/07/2024	02/07/2024												
										A071102	Failure to Interrogate	02/07/2024	02/07/2024												
F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery					02/07/2024	02/07/2024																
		A071102	Failure to Interrogate					02/07/2024	02/07/2024																
F1905	Device Revision or Replacement					A070504	Premature Discharge of Battery	02/07/2024	02/07/2024																
						A071102	Failure to Interrogate	02/07/2024	02/07/2024																

8254	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071102	Failure to Interrogate	02/07/2024	02/07/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8255	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
8256	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8257	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8258	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	14/04/2024	14/04/2024
									A0705	Battery Problem	14/04/2024	14/04/2024
									A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	14/04/2024	14/04/2024
									A0705	Battery Problem	14/04/2024	14/04/2024
									A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
							F1903	Device Explanation	A0508	Noise, Audible	14/04/2024	14/04/2024
									A0705	Battery Problem	14/04/2024	14/04/2024
									A070504	Premature Discharge of Battery	14/04/2024	14/04/2024
8259	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8260	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072201	High Impedance		
									A072202	Low Impedance		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801 A070909 A072201 A072202 A090801 A070909 A072201 A072202 A090801 A070909	Signal Artifact/Noise Oversensing High Impedance Low Impedance Signal Artifact/Noise Oversensing High Impedance Low Impedance Signal Artifact/Noise Oversensing			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201 A072202 A090801 A070909 A072201 A072202 A090801 A070909	High Impedance Low Impedance Signal Artifact/Noise Oversensing High Impedance Low Impedance Signal Artifact/Noise Oversensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201 A072202 A090801 A070909	High Impedance Low Impedance Signal Artifact/Noise Oversensing			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072201 A072202 A090801	Oversensing High Impedance Low Impedance Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A072201 A072202 A090801	Oversensing High Impedance Low Impedance Signal Artifact/Noise			
6261	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A07112 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
						E2311	Discomfort	A07112 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation			
						E2330	Pain	A07112 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07112 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation			
						F23	Unexpected Medical Intervention	A07112 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation			
6262	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024
						F12	Serious Injury/ Illness/ Impairment	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024	
						F23	Unexpected Medical Intervention	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024
						F12	Serious Injury/ Illness/ Impairment	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024	
						F23	Unexpected Medical Intervention	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024
						F12	Serious Injury/ Illness/ Impairment	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024	
						F23	Unexpected Medical Intervention	A07112 A1206	Pacing Problem Misconnection	03/06/2024	03/06/2024	
6263	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator		E210401	Shock from Patient Lead(s)	A07112 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A07112 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation			
6264	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
						F1001	Absence of Treatment	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation			
						F1203	Life Threatening Illness or Injury	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation			
6265	2024	All other reportable incidents	47940	Triple-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07112 A0712	Pacing Problem Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07112 A0712	Pacing Problem Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07112 A0712	Pacing Problem Pacing Problem		
6266	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
						F12	Serious Injury/ Illness/ Impairment	A13	Communication or Transmission Problem			
						F2307	Reprogramming of Device	A13	Communication or Transmission Problem			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
						F12	Serious Injury/ Illness/ Impairment	A13	Communication or Transmission Problem			
						F2307	Reprogramming of Device	A13	Communication or Transmission Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
						F12	Serious Injury/ Illness/ Impairment	A13	Communication or Transmission Problem			
						F2307	Reprogramming of Device	A13	Communication or Transmission Problem			
6267	2024	Death	35852	Single-chamber implantable defibrillator		E060109	Tachycardia	A070909 A071202 A071302 A090801 A1301	Oversensing Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
						E210401	Shock from Patient Lead(s)	A070909 A071202 A071302 A090801 A1301	Oversensing Inaccurate Synchronization Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal			
						F02	Death	A070909 A071202	Oversensing Inaccurate Synchronization			

								Exposure	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6270	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	23/05/2024	23/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	23/05/2024	23/05/2024
							F1905	Device Revision or Replacement	A070909	Oversensing	23/05/2024	23/05/2024
6271	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A070910	Undersensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F1908	Prolonged Surgery	A070909	Oversensing		
									A070910	Undersensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
6272	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F28	No Health Consequences or Impact	A072201	High Impedance		
6273	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F1905	Device Revision or Replacement	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F2203	Imaging Required	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F1905	Device Revision or Replacement	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F2203	Imaging Required	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F1905	Device Revision or Replacement	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F2203	Imaging Required	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025
									A070909	Oversensing	10/03/2025	10/03/2025
									A072201	High Impedance	10/03/2025	10/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	10/03/2025	10/03/2025
									A0709	Device Sensing Problem	10/03/2025	10/03/2025

						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801 A070909 A072001 A090801	Signal Artifact/Noise Oversensing Electromagnetic Interference Signal Artifact/Noise		
								F26	No Health Consequences or Impact	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
								F26	No Health Consequences or Impact	A070909 A072001	Oversensing Electromagnetic Interference		
6279	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801 A090805	Signal Artifact/Noise Incorrect Measurement		01/01/2024	31/12/2024
							F26	No Health Consequences or Impact	A090805	Incorrect Measurement		01/01/2024	31/12/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement		01/01/2024	31/12/2024
							F26	No Health Consequences or Impact	A090805	Incorrect Measurement		01/01/2024	31/12/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement		01/01/2024	31/12/2024
							F26	No Health Consequences or Impact	A090805	Incorrect Measurement		01/01/2024	31/12/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement		01/01/2024	31/12/2024
							F26	No Health Consequences or Impact	A090805	Incorrect Measurement		01/01/2024	31/12/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement		01/01/2024	31/12/2024
							F26	No Health Consequences or Impact	A090805	Incorrect Measurement		01/01/2024	31/12/2024
6280	2024	All other reportable incidents			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		05/12/2023	05/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings		05/12/2023	05/12/2023
									A070504	Premature Discharge of Battery		05/12/2023	05/12/2023
							F1903	Device Explanation	A070504	Incorrect, Inadequate or Imprecise Result or Readings		05/12/2023	05/12/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		05/12/2023	05/12/2023
6281	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm			
6282	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001 A090801	Electromagnetic Interference Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference			
6283	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
6284	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909 A070910 A071302 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							F2203	Imaging Required	A070909 A070910 A071302 A1301	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
6285	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	Tachycardia	A0712	Pacing Problem			

							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
8289	2024	Death	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071201	Failure to Convert Rhythm		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F02	Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8290	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A16	Protective Measures Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A16	Protective Measures Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A16	Protective Measures Problem		
									A0712	Pacing Problem		
									A16	Protective Measures Problem		
8291	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
8292	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071204	No Pacing		
									A070909	Oversensing		
									A071204	No Pacing		
8293	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
8294	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/06/2024	18/06/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/06/2024	18/06/2024
									A070504	Premature Discharge of Battery	18/06/2024	18/06/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/06/2024	18/06/2024
									A070504	Premature Discharge of Battery	18/06/2024	18/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/06/2024	18/06/2024
8295	2024		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0202	Defective Component		
									A070602	Delayed Charge Time		
							F26	No Health Consequences or Impact	A0202	Defective Component		

8306	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
							F1903	Device Explanation	A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
							F1903	Device Explanation	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
					CT258	Implantable defibrillators	E2104	Electric Shock	A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
							F1903	Device Explanation	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
							F1903	Device Explanation	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
					CT266	Implantable cardiac electrical stimulators	E2104	Electric Shock	A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
									A070909	Oversensing	08/12/2023	08/12/2023
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
							F1903	Device Explanation	A070909	Oversensing	08/12/2023	08/12/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/12/2023	08/12/2023
									A090801	Signal Artifact/Noise	08/12/2023	08/12/2023
8307	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
8308	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/06/2024	27/06/2024
									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/06/2024	27/06/2024
									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/06/2024	27/06/2024
									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/06/2024	27/06/2024
									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/06/2024	27/06/2024
									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/06/2024	27/06/2024
									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
					CT266	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	27/06/2024	27/06/2024
									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	27/06/2024	27/06/2024
									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	27/06/2024	27/06/2024

									A070504	Premature Discharge of Battery	27/06/2024	27/06/2024
8309	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/06/2024	27/06/2024
							F26	No Health Consequences or Impact	A072201	High Impedance		
8310	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
8311	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
							F19	Surgical Intervention	A072201	High Impedance		
8312	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F1901	Additional Surgery	A071204	No Pacing		
									A070909	Overensing		
									A071204	No Pacing		
8313	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8314	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
8315	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0712	Pacing Problem		
8316	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
							F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
					CT1150	Defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
							F23	Unexpected Medical Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
					CT258	Implantable defibrillators	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	28/11/2023	28/11/2023
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2023	28/11/2023

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					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
8322	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
							F24	Insufficient Health Impact Information	A0508 A070102 A070504	Noise, Audible High Capture Threshold Premature Discharge of Battery		
8323	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8324	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
8325	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0608	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	04/02/2025	04/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0608	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	04/02/2025	04/02/2025

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/02/2025	04/02/2025
8326	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/02/2025	04/02/2025
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1107	Data Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071301	Failure to Read Input Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1107	Data Problem		
									A1301	Failure to Read Input Signal		
8327	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8328	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E011902	Presyncope	A0709	Device Sensing Problem		
							E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	E011902	Presyncope	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							E060109	Tachycardia	A0709	Device Sensing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E011902	Presyncope	A0709	Device Sensing Problem		
							E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
8329	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8330	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070102	High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A070102	High Capture Threshold		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070102	High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A070102	High Capture Threshold		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070102	High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A070102	High Capture Threshold		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070102	High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A070102	High Capture Threshold		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070102	High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A070102	High Capture Threshold		
8331	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event		
									A25	No Apparent Adverse Event		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event		
									A25	No Apparent Adverse Event		
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event		
									A25	No Apparent Adverse Event		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event		
									A25	No Apparent Adverse Event		
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event		
									A25	No Apparent Adverse Event		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event		
									A25	No Apparent Adverse Event		
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event		
									A25	No Apparent Adverse Event		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event		
									A25	No Apparent Adverse Event		
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event		
8332	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/10/2024	02/10/2024
									A070504	Premature Discharge of Battery	02/10/2024	02/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/10/2024	02/10/2024
									A070504	Premature Discharge of Battery	02/10/2024	02/10/2024
							F1903	Device Explanation	A0705	Battery Problem	02/10/2024	02/10/2024
									A070504	Premature Discharge of Battery	02/10/2024	02/10/2024
									A0705	Battery Problem	02/10/2024	02/10/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/10/2024	02/10/2024
									A070504	Premature Discharge of Battery	02/10/2024	02/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	02/10/2024	02/10/2024
									A070504	Premature Discharge of Battery	02/10/2024	02/10/2024
							F1903	Device Explanation	A0705	Battery Problem	02/10/2024	02/10/2024
									A070504	Premature Discharge of Battery	02/10/2024	02/10/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	02/10/2024	02/10/2024

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	08/07/2024	08/07/2024		
									A1304	Telemetry Discrepancy	08/07/2024	08/07/2024		
							F08	Hospitalization or Prolonged Hospitalization	A0711	Interrogation Problem	08/07/2024	08/07/2024		
									A1304	Telemetry Discrepancy	08/07/2024	08/07/2024		
							F1905	Device Revision or Replacement	A0711	Interrogation Problem	08/07/2024	08/07/2024		
									A1304	Telemetry Discrepancy	08/07/2024	08/07/2024		
									A0508	Noise, Audible	28/11/2024	28/11/2024		
									A0705	Battery Problem	28/11/2024	28/11/2024		
6336	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/11/2024	28/11/2024		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2024	28/11/2024		
									A0508	Noise, Audible	28/11/2024	28/11/2024		
									A0705	Battery Problem	28/11/2024	28/11/2024		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/11/2024	28/11/2024		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2024	28/11/2024		
									A0508	Noise, Audible	28/11/2024	28/11/2024		
									A0705	Battery Problem	28/11/2024	28/11/2024		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/11/2024	28/11/2024		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2024	28/11/2024		
									A0508	Noise, Audible	28/11/2024	28/11/2024		
									A0705	Battery Problem	28/11/2024	28/11/2024		
									A070504	Premature Discharge of Battery	28/11/2024	28/11/2024		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/11/2024	28/11/2024		
6337	2024		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	03/07/2024	03/07/2024		
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event	03/07/2024	03/07/2024		
							CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	03/07/2024	03/07/2024
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event	03/07/2024	03/07/2024		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event	03/07/2024	03/07/2024		
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event	03/07/2024	03/07/2024		
6338	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance				
									A0908	Incorrect, Inadequate or Imprecise Result or Readings				
							F26	No Health Consequences or Impact	A072201	High Impedance				
									A0908	Incorrect, Inadequate or Imprecise Result or Readings				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance				
									A0908	Incorrect, Inadequate or Imprecise Result or Readings				
							F26	No Health Consequences or Impact	A072201	High Impedance				
									A0908	Incorrect, Inadequate or Imprecise Result or Readings				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance				
									A0908	Incorrect, Inadequate or Imprecise Result or Readings				
							F26	No Health Consequences or Impact	A072201	High Impedance				
									A0908	Incorrect, Inadequate or Imprecise Result or Readings				
				A072201	High Impedance									
				A0908	Incorrect, Inadequate or Imprecise Result or Readings									
				A072201	High Impedance									
				A0908	Incorrect, Inadequate or Imprecise Result or Readings									
6339	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
									A070101	Failure to Capture				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture				
6340	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
6341	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011902	Presyncope	A071301	Failure to Deliver Shock/Simulation				
							E060109	Tachycardia	A071301	Failure to Deliver Shock/Simulation				
6342	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	P05	Delay to Treatment/ Therapy	A071301	Failure to Deliver Shock/Simulation				
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Simulation				
									A0508	Noise, Audible	19/09/2024	19/09/2024		
									A070504	Premature Discharge of Battery	19/09/2024	19/09/2024		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/09/2024	19/09/2024		
									A0508	Noise, Audible	19/09/2024	19/09/2024		
									A070504	Premature Discharge of Battery	19/09/2024	19/09/2024		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/09/2024	19/09/2024		
									A0508	Noise, Audible	19/09/2024	19/09/2024		
									A070504	Premature Discharge of Battery	19/09/2024	19/09/2024		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/09/2024	19/09/2024		
									A070504	Premature Discharge of Battery	19/09/2024	19/09/2024		
6343	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Simulation				
									A090805	Incorrect Measurement				
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Simulation				
									A090805	Incorrect Measurement				
					CT258	Implantable defibrillators	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Simulation				
									A090805	Incorrect Measurement				
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Simulation				
									A090805	Incorrect Measurement				
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071301	Failure to Deliver Shock/Simulation				
									A090805	Incorrect Measurement				
							F23	Unexpected Medical Intervention	A071301	Failure to Deliver Shock/Simulation				
									A090805	Incorrect Measurement				
6344	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060104	Bradycardia	A0712	Pacing Problem				
									A072001	Electromagnetic Interference				
							F11	Non-Serious Injury/ Illness/ Impairment	A0712	Pacing Problem				
									A072001	Electromagnetic Interference				
					CT258	Implantable defibrillators	E060104	Bradycardia	A0712	Pacing Problem				
									A072001	Electromagnetic Interference				
							F11	Non-Serious Injury/ Illness/ Impairment	A0712	Pacing Problem				
									A072001	Electromagnetic Interference				
CT2866	Implantable cardiac electrical stimulators	E060104	Bradycardia	A0712	Pacing Problem									
				A072001	Electromagnetic Interference									
		F11	Non-Serious Injury/ Illness/ Impairment	A0712	Pacing Problem									
				A072001	Electromagnetic Interference									
6345	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
									A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
									A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
									A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023		

6346	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/03/2023	29/03/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
						CT1150	F2203	Imaging Required	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
						CT263	F2203	Imaging Required	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
6347	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0203	Defective Device	18/07/2024	18/07/2024
									A040101	Fracture	18/07/2024	18/07/2024
									A070909	Oversensing	18/07/2024	18/07/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	18/07/2024	18/07/2024
									A090801	Signal Artifact/Noise	18/07/2024	18/07/2024
									A090801	Signal Artifact/Noise	18/07/2024	18/07/2024
							F08	Hospitalization or Prolonged Hospitalization	A0203	Defective Device	18/07/2024	18/07/2024
									A040101	Fracture	18/07/2024	18/07/2024
									A070909	Oversensing	18/07/2024	18/07/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	18/07/2024	18/07/2024
									A090801	Signal Artifact/Noise	18/07/2024	18/07/2024
									A0203	Defective Device	18/07/2024	18/07/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A040101	Fracture	18/07/2024	18/07/2024
									A070909	Oversensing	18/07/2024	18/07/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	18/07/2024	18/07/2024
									A090801	Signal Artifact/Noise	18/07/2024	18/07/2024
									A0203	Defective Device	18/07/2024	18/07/2024
									A040101	Fracture	18/07/2024	18/07/2024
6348	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	19/09/2024	19/09/2024
									A070504	Premature Discharge of Battery	19/09/2024	19/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/09/2024	19/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	19/09/2024	19/09/2024
									A070504	Premature Discharge of Battery	19/09/2024	19/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/09/2024	19/09/2024
							F1905	Device Revision or Replacement	A0508	Noise, Audible	19/09/2024	19/09/2024
									A070504	Premature Discharge of Battery	19/09/2024	19/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/09/2024	19/09/2024
									A0705	Battery Problem	16/07/2024	16/07/2024
									A070504	Premature Discharge of Battery	16/07/2024	16/07/2024
									A071102	Failure to Interrogate	16/07/2024	16/07/2024
6349	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	16/07/2024	16/07/2024
									A070504	Premature Discharge of Battery	16/07/2024	16/07/2024
									A071102	Failure to Interrogate	16/07/2024	16/07/2024
							F26	No Health Consequences or Impact	A0705	Battery Problem	16/07/2024	16/07/2024
									A070504	Premature Discharge of Battery	16/07/2024	16/07/2024
									A071102	Failure to Interrogate	16/07/2024	16/07/2024
6350	2024	All other reportable incidents			CT258	Implantable defibrillators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E060102	Atrial Fibrillation	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
6351	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		

					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8352	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8353	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/11/2024	11/11/2024
8354	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/06/2023	27/06/2023
8355	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/12/2024	05/12/2024
8356	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	20/09/2024	20/09/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	20/09/2024	20/09/2024
									A072201	High Impedance	20/09/2024	20/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024
									A0709	Device Sensing Problem	20/09/2024	20/09/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	20/09/2024	20/09/2024
									A072201	High Impedance	20/09/2024	20/09/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024
									A0709	Device Sensing Problem	20/09/2024	20/09/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	20/09/2024	20/09/2024
									A072201	High Impedance	20/09/2024	20/09/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024
									A0709	Device Sensing Problem	20/09/2024	20/09/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	20/09/2024	20/09/2024
									A072201	High Impedance	20/09/2024	20/09/2024
							F22	Unexpected Diagnostic Intervention	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024
									A0709	Device Sensing Problem	20/09/2024	20/09/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	20/09/2024	20/09/2024
									A072201	High Impedance	20/09/2024	20/09/2024
							F2203	Imaging Required	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024
									A0709	Device Sensing Problem	20/09/2024	20/09/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	20/09/2024	20/09/2024
									A072201	High Impedance	20/09/2024	20/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024
8357	2024		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0201	Product Quality Problem		
							F1905	Device Revision or Replacement	A0203	Defective Device		
									A0201	Product Quality Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
							F1905	Device Revision or Replacement	A0201	Product Quality Problem		
									A0203	Defective Device		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0201	Product Quality Problem		
							F1905	Device Revision or Replacement	A0203	Defective Device		
									A0201	Product Quality Problem		
									A0203	Defective Device		
8358	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	05/07/2024	05/07/2024
									A040101	Fracture	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
									A090801	Signal Artifact/Noise	05/07/2024	05/07/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A040101	Fracture	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
									A090801	Signal Artifact/Noise	05/07/2024	05/07/2024
							F1905	Device Revision or Replacement	A040101	Fracture	05/07/2024	05/07/2024
									A070909	Oversensing	05/07/2024	05/07/2024
									A090801	Signal Artifact/Noise	05/07/2024	05/07/2024
8359	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/05/2024	24/05/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	24/05/2024	24/05/2024
8360	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		

8365	2024		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	01/08/2024	01/08/2024
8366	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F26	No Health Consequences or Impact	A0705	Battery Problem		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators			A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
					CT263	Cardiographs and associated devices			A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators			A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
8367	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices			A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
							F1905	Device Revision or Replacement	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
					CT1150	Defibrillators			A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
							F1905	Device Revision or Replacement	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
					CT258	Implantable defibrillators			A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
							F1905	Device Revision or Replacement	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
					CT263	Cardiographs and associated devices			A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
							F1905	Device Revision or Replacement	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
					CT2866	Implantable cardiac electrical stimulators			A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024

							F08	Hospitalization or Prolonged Hospitalization	A0508	Noise, Audible	23/08/2024	23/08/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
									A0508	Noise, Audible	23/08/2024	23/08/2024
									A070504	Premature Discharge of Battery	23/08/2024	23/08/2024
8368	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
8369	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
							F26	No Health Consequences or Impact	A071102	Failure to Interrogate		
8370	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
							F26	No Health Consequences or Impact	A071102	Failure to Interrogate		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
							F26	No Health Consequences or Impact	A071102	Failure to Interrogate		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate		
							F26	No Health Consequences or Impact	A071102	Failure to Interrogate		
8371	2024	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0611	Heart Failure/Congestive Heart Failure	A070504	Premature Discharge of Battery	05/08/2024	05/08/2024
							E1014	Gastrointestinal Hemorrhage	A070504	Premature Discharge of Battery	05/08/2024	05/08/2024
							F02	Death	A070504	Premature Discharge of Battery	05/08/2024	05/08/2024
8372	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
8373	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	19/07/2024	19/07/2024
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise	19/07/2024	19/07/2024
									A05	Mechanical Problem	19/07/2024	19/07/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	19/07/2024	19/07/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	19/07/2024	19/07/2024
									A090801	Signal Artifact/Noise	19/07/2024	19/07/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	19/07/2024	19/07/2024
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise	19/07/2024	19/07/2024
									A05	Mechanical Problem	19/07/2024	19/07/2024
									A090801	Signal Artifact/Noise	19/07/2024	19/07/2024
8374	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	19/07/2024	19/07/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

							F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
					CT2866	implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
8375	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/08/2024	13/08/2024
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	13/08/2024	13/08/2024
8376	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	03/06/2024	03/06/2024
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise	03/06/2024	03/06/2024
									A070909	Oversensing	03/06/2024	03/06/2024
									A090801	Signal Artifact/Noise	03/06/2024	03/06/2024
8377	2024	All other reportable incidents	47940	Triple-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102	High Capture Threshold		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102	High Capture Threshold		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102	High Capture Threshold		
8378	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
8379	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
8380	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
8381	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
8382	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8383	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8384	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
8385	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
8386	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8387	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	29/07/2024	29/07/2024
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance	29/07/2024	29/07/2024
							F1903	Device Explanation	A072201	High Impedance	29/07/2024	29/07/2024
8388	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E0601	Arrhythmia	A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E0601	Arrhythmia	A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8389	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact		A0705	Battery Problem		
									A070504	Premature Discharge of Battery		

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908 A0705 A070504 A0908	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
8390	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	06/12/2024	06/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	06/12/2024	06/12/2024
							F1905	Device Revision or Replacement	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	06/12/2024	06/12/2024
8391	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	12/11/2024	12/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	12/11/2024	12/11/2024
							F1905	Device Revision or Replacement	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	12/11/2024	12/11/2024
8392	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070504 A071302	Premature Discharge of Battery Inappropriate/Inadequate Shock/Stimulation		
8393	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
							F2307	Reprogramming of Device	A071302 A0712	Inappropriate/Inadequate Shock/Stimulation Pacing Problem		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
							F2307	Reprogramming of Device	A071302 A0712	Inappropriate/Inadequate Shock/Stimulation Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0712	Pacing Problem		
8394	2024	All other reportable incidents			CT258	Implantable defibrillators	E2104	Electric Shock	A071302 A070909 A071302	Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A0709	Device Sensing Problem		

										A070909	Oversensing		
							F23	Unexpected Medical Intervention		A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
6395	2024	All other reportable incidents				CT258	E210401	Shock from Patient Lead(s)		A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization		A1301	Failure to Read Input Signal		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
6396	2024	All other reportable incidents				CT258	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
							F23	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
6397	2024	All other reportable incidents				CT258	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	16/07/2024	16/07/2024
							F08	Hospitalization or Prolonged Hospitalization		A0908	Incorrect, Inadequate or Imprecise Result or Readings	16/07/2024	16/07/2024
										A070504	Premature Discharge of Battery	16/07/2024	16/07/2024
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	16/07/2024	16/07/2024
							F1903	Device Explanation		A070504	Premature Discharge of Battery	16/07/2024	16/07/2024
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	16/07/2024	16/07/2024
6398	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
						CT1150	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
						CT258	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
						CT263	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
						CT2866	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	08/07/2025	08/07/2025
6399	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						CT1150	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						CT258	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						CT263	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						CT2866	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
6400	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1150	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
						CT258	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
						CT2866	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A070909	Oversensing		
6401	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator		CT258	E2403	No Clinical Signs, Symptoms or Conditions		A0712	Racing Problem		
										A071204	No Pacing		
							F23	Unexpected Medical Intervention		A070909	Oversensing		
										A0712	Pacing Problem		
										A071204	No Pacing		
6402	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator		CT1010	E210401	Shock from Patient Lead(s)		A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury		A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
						CT1150	E210401	Shock from Patient Lead(s)		A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury		A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
						CT258	E210401	Shock from Patient Lead(s)		A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury		A0709	Device Sensing Problem		

							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8406	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F1903	Device Explanation	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F1903	Device Explanation	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F1903	Device Explanation	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F1903	Device Explanation	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
							F1903	Device Explanation	A0705	Battery Problem	03/11/2023	03/11/2023
									A070504	Premature Discharge of Battery	03/11/2023	03/11/2023
8407	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8408	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8409	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
							F23	Unexpected Medical Intervention	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
							F23	Unexpected Medical Intervention	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
							F23	Unexpected Medical Intervention	A0712	Pacing Problem	03/06/2024	03/06/2024
									A1206	Misconnection	03/06/2024	03/06/2024
8410	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device		
									A070909	Oversensing		
									A070910	Undersensing		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A0203	Defective Device		
									A070909	Oversensing		
									A070910	Undersensing		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
8411	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		

6412	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
						F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
						F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
						F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator			
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
						F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset			
							A1605	Reset Problem				
							A160503	Inappropriate or Unexpected Reset				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
						F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset			
							A1605	Reset Problem				
							A160503	Inappropriate or Unexpected Reset				
6413	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset		
						F26	No Health Consequences or Impact	A1605	Reset Problem			
							A160503	Inappropriate or Unexpected Reset				
							A1605	Reset Problem				
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
						F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset			
							A1605	Reset Problem				
							A160503	Inappropriate or Unexpected Reset				
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
						F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset			
							A1605	Reset Problem				
							A160503	Inappropriate or Unexpected Reset				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
						F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset			
6414	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
						F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation			
							A070912	Incorrect Interpretation of Signal				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							A0712	Pacing Problem				
							A071301	Failure to Deliver Shock/Stimulation				
						F1001	Absence of Treatment	A0709	Device Sensing Problem			
							A0712	Pacing Problem				
							A071301	Failure to Deliver Shock/Stimulation				
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
							A0712	Pacing Problem				
							A071301	Failure to Deliver Shock/Stimulation				
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
6415	2024	Death	37265	Dual-chamber implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0712	Pacing Problem		
						F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation			
							A0709	Device Sensing Problem				
						F1203	Life Threatening Illness or Injury	A0712	Pacing Problem			
							A071301	Failure to Deliver Shock/Stimulation				
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
							A0712	Pacing Problem				
							A071301	Failure to Deliver Shock/Stimulation				
							A0709	Device Sensing Problem				
							A0712	Pacing Problem				
							A071301	Failure to Deliver Shock/Stimulation				
						E060109	Tachycardia	A0709	Device Sensing Problem			
						F1001	Absence of Treatment	A0712	Pacing Problem			
							A071301	Failure to Deliver Shock/Stimulation				
6416	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
						F12	Serious Injury/ Illness/ Impairment	A13	Communication or Transmission Problem			
						F2307	Reprogramming of Device	A13	Communication or Transmission Problem			
							A13	Communication or Transmission Problem				
6417	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
						F12	Serious Injury/ Illness/ Impairment	A13	Communication or Transmission Problem			
						F2307	Reprogramming of Device	A13	Communication or Transmission Problem			
							A13	Communication or Transmission Problem				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
						F12	Serious Injury/ Illness/ Impairment	A13	Communication or Transmission Problem			
6418	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance			
							A072201	High Impedance				
							A072201	High Impedance				

8419	2024	All other reportable incidents			CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/08/2024	27/08/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/08/2024	27/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/08/2024	27/08/2024
							F1905	Device Revision or Replacement	A070504	Incorrect, Inadequate or Imprecise Result or Readings	27/08/2024	27/08/2024
							A0908		A0908	Premature Discharge of Battery	27/08/2024	27/08/2024
8420	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	27/08/2024	27/08/2024
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							A070909		A070909	Oversensing		
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8421	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2024	21/10/2024
8422	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/03/2024	18/03/2024
							A070504		A070504	Premature Discharge of Battery	18/03/2024	18/03/2024
							A0908		A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/03/2024	18/03/2024
8423	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F24	Insufficient Health Impact Information	A070504	Premature Discharge of Battery		
							A0705		A0705	Battery Problem		
							A070504		A070504	Premature Discharge of Battery		
8424	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071301	Failure to Deliver Shock/Stimulation		
							A0709		A0709	Device Sensing Problem		
							A071301		A071301	Failure to Deliver Shock/Stimulation		
8425	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							A0709		A0709	Device Sensing Problem		
							A0712		A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							A0709		A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
							A0712		A0712	Pacing Problem		
					CT263	Cardiographs end associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							A0709		A0709	Device Sensing Problem		
							A0712		A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							A0709		A0709	Device Sensing Problem		
							A0712		A0712	Pacing Problem		
8426	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							A072001		A072001	Electromagnetic Interference		
							A090801		A090801	Signal Artifact/Noise		
							A160105		A160105	False Alarm		
							F26	No Health Consequences or Impact	A070909	Oversensing		
							A072001		A072001	Electromagnetic Interference		
							A090801		A090801	Signal Artifact/Noise		
							A160105		A160105	False Alarm		
8427	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
							A150201		A150201	Positioning Failure		

		F05	Delay to Treatment/ Therapy	A23	Use of Device Problem		
				A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
		F05	Delay to Treatment/ Therapy	A0401	Break		
				A150201	Positioning Failure		
				A23	Use of Device Problem		
CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		

									A150201	Positioning Failure		
								F05	Delay to Treatment/ Therapy	A23	Use of Device Problem	
										A0401	Break	
										A150201	Positioning Failure	
										A23	Use of Device Problem	
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
									A150201	Positioning Failure		
							F05	Delay to Treatment/ Therapy	A23	Use of Device Problem		
									A0401	Break		
									A150201	Positioning Failure		
									A23	Use of Device Problem		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
									A150201	Positioning Failure		
							F05	Delay to Treatment/ Therapy	A23	Use of Device Problem		
									A0401	Break		
									A150201	Positioning Failure		
									A23	Use of Device Problem		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
									A150201	Positioning Failure		
							F05	Delay to Treatment/ Therapy	A23	Use of Device Problem		
									A0401	Break		
									A150201	Positioning Failure		
									A23	Use of Device Problem		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
									A150201	Positioning Failure		
							F05	Delay to Treatment/ Therapy	A23	Use of Device Problem		
									A0401	Break		
									A150201	Positioning Failure		
									A23	Use of Device Problem		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions	A0401	Break		
									A150201	Positioning Failure		
							F05	Delay to Treatment/ Therapy	A23	Use of Device Problem		
									A0401	Break		
									A150201	Positioning Failure		
									A23	Use of Device Problem		
6428	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A05	Mechanical Problem		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A05	Mechanical Problem		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A05	Mechanical Problem		
									A072201	High Impedance		
6429	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070101	Failure to Capture		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A070101	Failure to Capture		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
							F1001	Absence of Treatment	A070101	Failure to Capture		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
6430	2024		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0601	Arrhythmia	A25	No Apparent Adverse Event	26/06/2024	26/06/2024
							F02	Death	A25	No Apparent Adverse Event	26/06/2024	26/06/2024
					CT258	Implantable defibrillators	E0601	Arrhythmia	A25	No Apparent Adverse Event	26/06/2024	26/06/2024
							F02	Death	A25	No Apparent Adverse Event	26/06/2024	26/06/2024
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A25	No Apparent Adverse Event	26/06/2024	26/06/2024
							F02	Death	A25	No Apparent Adverse Event	26/06/2024	26/06/2024
6431	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2312	Fatigue	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							P2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6432	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2024	19/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/11/2024	19/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2024	19/11/2024

							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/11/2024	19/11/2024
									A070504	Premature Discharge of Battery	19/11/2024	19/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	19/11/2024	19/11/2024
8433	2024	Death	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT141	Electrodes/Leads and associated devices	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT145	Cardiovascular devices	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT233	Surgical	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2406	Implantable	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2407	Active implantable	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2985	Active	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3001	Implantable metal	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3002	Implantable synthetic polymer	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F02	Death	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3006	Implantable inorganic material	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F02	Death		A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT3007	implantable ceramic	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F02	Death		A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT314	Electrically powered	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F02	Death		A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT321	Long-term surgical invasive	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F02	Death		A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT449	Generators and associated devices	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F02	Death		A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT981	Single use	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F02	Death		A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT983	Surgical invasive	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F02	Death		A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8434	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
						F26	No Health Consequences or Impact		A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
						F26	No Health Consequences or Impact		A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
						F26	No Health Consequences or Impact		A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
						F26	No Health Consequences or Impact		A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
						F26	No Health Consequences or Impact		A0705	Battery Problem		
									A160601	Premature Elective Replacement Indicator		
									A160602	Premature End-of-Life Indicator		
8435	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A070504	Premature Discharge of Battery		
8436	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F26	No Health Consequences or Impact		A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
8437	2024	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E011903	Syncope/Fainting	A070101	Failure to Capture	02/09/2024	02/09/2024
									A0712	Pacing Problem	02/09/2024	02/09/2024
						E060101	Aysstole		A070101	Failure to Capture	02/09/2024	02/09/2024
									A0712	Pacing Problem	02/09/2024	02/09/2024
						E233001	Chest Pain		A070101	Failure to Capture	02/09/2024	02/09/2024
									A0712	Pacing Problem	02/09/2024	02/09/2024
						F02	Death		A070101	Failure to Capture	02/09/2024	02/09/2024
									A0712	Pacing Problem	02/09/2024	02/09/2024
						F2306	Resuscitation		A070101	Failure to Capture	02/09/2024	02/09/2024

							F2307	Reprogramming of Device	A07012	Pacing Problem	02/09/2024	02/09/2024
									A070101	Failure to Capture	02/09/2024	02/09/2024
									A0712	Pacing Problem	02/09/2024	02/09/2024
					CT1150	Defibrillators	E011903	Syncope/Fainting	A070101	Failure to Capture	02/09/2024	02/09/2024
							E060101	Asystole	A070101	Failure to Capture	02/09/2024	02/09/2024
							E233001	Chest Pain	A0712	Pacing Problem	02/09/2024	02/09/2024
							F02	Death	A070101	Failure to Capture	02/09/2024	02/09/2024
							F2306	Resuscitation	A0712	Pacing Problem	02/09/2024	02/09/2024
							F2307	Reprogramming of Device	A070101	Failure to Capture	02/09/2024	02/09/2024
									A0712	Pacing Problem	02/09/2024	02/09/2024
					CT258	Implantable defibrillators	E011903	Syncope/Fainting	A070101	Failure to Capture	02/09/2024	02/09/2024
							E060101	Asystole	A0712	Pacing Problem	02/09/2024	02/09/2024
							E233001	Chest Pain	A070101	Failure to Capture	02/09/2024	02/09/2024
							F02	Death	A0712	Pacing Problem	02/09/2024	02/09/2024
							F2306	Resuscitation	A070101	Failure to Capture	02/09/2024	02/09/2024
							F2307	Reprogramming of Device	A0712	Pacing Problem	02/09/2024	02/09/2024
					CT263	Cardiographs and associated devices	E011903	Syncope/Fainting	A070101	Failure to Capture	02/09/2024	02/09/2024
							E060101	Asystole	A0712	Pacing Problem	02/09/2024	02/09/2024
							E233001	Chest Pain	A070101	Failure to Capture	02/09/2024	02/09/2024
							F02	Death	A0712	Pacing Problem	02/09/2024	02/09/2024
							F2306	Resuscitation	A070101	Failure to Capture	02/09/2024	02/09/2024
							F2307	Reprogramming of Device	A0712	Pacing Problem	02/09/2024	02/09/2024
					CT2866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting	A070101	Failure to Capture	02/09/2024	02/09/2024
							E060101	Asystole	A0712	Pacing Problem	02/09/2024	02/09/2024
							E233001	Chest Pain	A070101	Failure to Capture	02/09/2024	02/09/2024
							F02	Death	A0712	Pacing Problem	02/09/2024	02/09/2024
							F2306	Resuscitation	A070101	Failure to Capture	02/09/2024	02/09/2024
							F2307	Reprogramming of Device	A0712	Pacing Problem	02/09/2024	02/09/2024
8438	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F26	No Health Consequences or Impact	A070909	Oversensing		
8439	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0619	Pericardial Effusion	A090801	Signal Artifact/Noise		
							E2103	Device Overstimulation of Tissue	A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E0619	Pericardial Effusion	A090801	Signal Artifact/Noise		
							E2103	Device Overstimulation of Tissue	A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E0619	Pericardial Effusion	A090801	Signal Artifact/Noise		
							E2103	Device Overstimulation of Tissue	A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E0619	Pericardial Effusion	A090801	Signal Artifact/Noise		
							E2103	Device Overstimulation of Tissue	A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E0619	Pericardial Effusion	A090801	Signal Artifact/Noise		
							E2103	Device Overstimulation of Tissue	A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
8440	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		

									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/10/2024	18/10/2024
6456	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
6457	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2303	Medication Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6458	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F08	Hospitalization or Prolonged Hospitalization	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
							F1905	Device Revision or Replacement	A13	Communication or Transmission Problem	22/09/2024	22/09/2024
									A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
									A13	Communication or Transmission Problem	22/09/2024	22/09/2024

6459	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator				
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator				
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator				
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator				
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator				
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator				
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator				
6460	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing				
									A0712	Pacing Problem				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing				
									A0712	Pacing Problem				
6461	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance				
							F26	No Health Consequences or Impact	A072201	High Impedance				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance				
							F26	No Health Consequences or Impact	A072201	High Impedance				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance				
6462	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance				
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/02/2025	18/02/2025		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/02/2025	18/02/2025		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/02/2025	18/02/2025		
6463	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem				
							F12	Serious Injury/ Illness/ Impairment	A1605	Reset Problem				
							F2307	Reprogramming of Device	A1605	Reset Problem				
							E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem				
							F12	Serious Injury/ Illness/ Impairment	A1605	Reset Problem				
							F2307	Reprogramming of Device	A1605	Reset Problem				
							E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem				
							F12	Serious Injury/ Illness/ Impairment	A1605	Reset Problem				
							F2307	Reprogramming of Device	A1605	Reset Problem				
							E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem				
					CT263	Cardiographs and associated devices	F12	Serious Injury/ Illness/ Impairment	A1605	Reset Problem				
							F2307	Reprogramming of Device	A1605	Reset Problem				
							E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem				
							F12	Serious Injury/ Illness/ Impairment	A1605	Reset Problem				
					CT2866	Implantable cardiac electrical stimulators	F2307	Reprogramming of Device	A1605	Reset Problem				
							E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem				
							F12	Serious Injury/ Illness/ Impairment	A1605	Reset Problem				
							F2307	Reprogramming of Device	A1605	Reset Problem				
6464	2024	All other reportable incidents			CT258	Implantable defibrillators	F2307	Reprogramming of Device	A1605	Reset Problem				
							E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem				
							F26	No Health Consequences or Impact	A1107	Data Problem				
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
6466	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A070602	Delayed Charge Time	13/01/2025	13/01/2025		
									A0711	Interrogation Problem	13/01/2025	13/01/2025		
									A071201	Failure to Convert Rhythm	13/01/2025	13/01/2025		
									A072202	Low Impedance	13/01/2025	13/01/2025		
							E2311	Discomfort	A070602	Delayed Charge Time	13/01/2025	13/01/2025		
									A0711	Interrogation Problem	13/01/2025	13/01/2025		
									A071201	Failure to Convert Rhythm	13/01/2025	13/01/2025		
									A072202	Low Impedance	13/01/2025	13/01/2025		
							E2340	Wound Dehiscence	A070602	Delayed Charge Time	13/01/2025	13/01/2025		
									A0711	Interrogation Problem	13/01/2025	13/01/2025		
									A071201	Failure to Convert Rhythm	13/01/2025	13/01/2025		
									A072202	Low Impedance	13/01/2025	13/01/2025		
							F08	Hospitalization or Prolonged Hospitalization	A070602	Delayed Charge Time	13/01/2025	13/01/2025		
									A0711	Interrogation Problem	13/01/2025	13/01/2025		
									A071201	Failure to Convert Rhythm	13/01/2025	13/01/2025		
									A072202	Low Impedance	13/01/2025	13/01/2025		
							F1203	Life Threatening Illness or Injury	A070602	Delayed Charge Time	13/01/2025	13/01/2025		
									A0711	Interrogation Problem	13/01/2025	13/01/2025		
									A071201	Failure to Convert Rhythm	13/01/2025	13/01/2025		
									A072202	Low Impedance	13/01/2025	13/01/2025		
							F1905	Device Revision or Replacement	A070602	Delayed Charge Time	13/01/2025	13/01/2025		
									A0711	Interrogation Problem	13/01/2025	13/01/2025		
									A071201	Failure to Convert Rhythm	13/01/2025	13/01/2025		
									A072202	Low Impedance	13/01/2025	13/01/2025		
							F23	Unexpected Medical Intervention	A070602	Delayed Charge Time	13/01/2025	13/01/2025		
									A0711	Interrogation Problem	13/01/2025	13/01/2025		
									A071201	Failure to Convert Rhythm	13/01/2025	13/01/2025		
									A072202	Low Impedance	13/01/2025	13/01/2025		
							F2306	Resuscitation	A070602	Delayed Charge Time	13/01/2025	13/01/2025		
									A0711	Interrogation Problem	13/01/2025	13/01/2025		
									A071201	Failure to Convert Rhythm	13/01/2025	13/01/2025		
									A072202	Low Impedance	13/01/2025	13/01/2025		
							CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									F26	No Health Consequences or Impact	A072201	High Impedance		
6468	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
									A070909	Oversensing				
									A072001	Electromagnetic Interference				
									A090801	Signal Artifact/Noise				
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem				
									A070909	Oversensing				
									A072001	Electromagnetic Interference				
									A090801	Signal Artifact/Noise				
							F2307	Reprogramming of Device	A0709	Device Sensing Problem				
									A070909	Oversensing				
									A072001	Electromagnetic Interference				
									A090801	Signal Artifact/Noise				
							CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		

									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F2307	Reprogramming of Device		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F2307	Reprogramming of Device		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F2307	Reprogramming of Device		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F12	Serious Injury/ Illness/ Impairment		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F2307	Reprogramming of Device		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
6469	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A150202	Malposition of Device		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A150202	Malposition of Device		
						F2203	Imaging Required		A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A150202	Malposition of Device		
6470	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A16	Protective Measures Problem		
						F26	No Health Consequences or Impact		A072001	Electromagnetic Interference		
6471	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A072201	High Impedance		
6472	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F12	Serious Injury/ Illness/ Impairment		A070912	Incorrect Interpretation of Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6473	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0618	Non Specific EKG/ECG Changes	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
						F11	Non-Serious Injury/ Illness/ Impairment		A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
6474	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/11/2024	05/11/2024
									F1901	Premature Discharge of Battery	05/11/2024	05/11/2024

6475	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A040101	Fracture	10/10/2024	10/10/2024
									A070909	Oversensing	10/10/2024	10/10/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	10/10/2024	10/10/2024
									A090801	Signal Artifact/Noise	10/10/2024	10/10/2024
									A12	Connection Problem	10/10/2024	10/10/2024
									A1301	Failure to Read Input Signal	10/10/2024	10/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A040101	Fracture	10/10/2024	10/10/2024
									A070909	Oversensing	10/10/2024	10/10/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	10/10/2024	10/10/2024
									A090801	Signal Artifact/Noise	10/10/2024	10/10/2024
									A12	Connection Problem	10/10/2024	10/10/2024
									A1301	Failure to Read Input Signal	10/10/2024	10/10/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A040101	Fracture	10/10/2024	10/10/2024
									A070909	Oversensing	10/10/2024	10/10/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	10/10/2024	10/10/2024
									A090801	Signal Artifact/Noise	10/10/2024	10/10/2024
									A12	Connection Problem	10/10/2024	10/10/2024
									A1301	Failure to Read Input Signal	10/10/2024	10/10/2024
							F1905	Device Revision or Replacement	A040101	Fracture	10/10/2024	10/10/2024
									A070909	Oversensing	10/10/2024	10/10/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	10/10/2024	10/10/2024
									A090801	Signal Artifact/Noise	10/10/2024	10/10/2024
									A12	Connection Problem	10/10/2024	10/10/2024
									A1301	Failure to Read Input Signal	10/10/2024	10/10/2024
							F2203	Imaging Required	A040101	Fracture	10/10/2024	10/10/2024
									A070909	Oversensing	10/10/2024	10/10/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	10/10/2024	10/10/2024
									A090801	Signal Artifact/Noise	10/10/2024	10/10/2024
									A12	Connection Problem	10/10/2024	10/10/2024
									A1301	Failure to Read Input Signal	10/10/2024	10/10/2024
6476	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	10/10/2024	10/10/2024
									A1301	Failure to Read Input Signal	10/10/2024	10/10/2024
									A070504	Battery Problem	08/04/2024	08/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/04/2024	08/04/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/04/2024	08/04/2024
									A0705	Battery Problem	08/04/2024	08/04/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/04/2024	08/04/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/04/2024	08/04/2024
									A0705	Battery Problem	08/04/2024	08/04/2024
									A070504	Premature Discharge of Battery	08/04/2024	08/04/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/04/2024	08/04/2024
									A070909	Oversensing		
6477	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
6478	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A0712	Pacing Problem		
6479	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E011903	Syncope/Fainting	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
6480	2024	All other reportable incidents			CT258	Implantable defibrillators	E0601	Arrhythmia	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E0602	Cardiac Arrest	A1301	Failure to Read Input Signal		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							E2007	Fall	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A0712	Pacing Problem		
							F0801	Intensive Care	A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		

							F23	Unexpected Medical Intervention	A071202	Pacing Problem		
									A071202	Inaccurate Synchronization		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
8481	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
8482	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8483	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F1905	Device Revision or Replacement	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F1905	Device Revision or Replacement	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
							F1905	Device Revision or Replacement	A0712	Pacing Problem	21/08/2024	21/08/2024
									A16	Protective Measures Problem	21/08/2024	21/08/2024
8484	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8485	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

6486	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A160105	False Alarm		
									A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A160105	False Alarm		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					F2307	Reprogramming of Device	A072001	Electromagnetic Interference				
							A090801	Signal Artifact/Noise				
							A160105	False Alarm				
							A0709	Device Sensing Problem				
							A070909	Oversensing				
							A072001	Electromagnetic Interference				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A160105	False Alarm		
									A0709	Device Sensing Problem		
F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing									
		A072001	Electromagnetic Interference									
		A090801	Signal Artifact/Noise									
		A160105	False Alarm									
		A0709	Device Sensing Problem									
		A070909	Oversensing									
F2307	Reprogramming of Device	A072001	Electromagnetic Interference									
		A090801	Signal Artifact/Noise									
		A160105	False Alarm									
		A0709	Device Sensing Problem									
		A070909	Oversensing									
		A072001	Electromagnetic Interference									
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem							
				A070909	Oversensing							
				A072001	Electromagnetic Interference							
				A090801	Signal Artifact/Noise							
				A160105	False Alarm							
				A0709	Device Sensing Problem							
		F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing							
				A072001	Electromagnetic Interference							
				A090801	Signal Artifact/Noise							
				A160105	False Alarm							
				A0709	Device Sensing Problem							
				A070909	Oversensing							
F2307	Reprogramming of Device	A072001	Electromagnetic Interference									
		A090801	Signal Artifact/Noise									
		A160105	False Alarm									
		A0709	Device Sensing Problem									
		A070909	Oversensing									
		A072001	Electromagnetic Interference									

6487	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	26/09/2024	26/09/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	26/09/2024	26/09/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	26/09/2024	26/09/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	26/09/2024	26/09/2024
6488	2024	All other reportable incidents			CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	26/09/2024	26/09/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	26/09/2024	26/09/2024
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem	22/02/2024	22/02/2024
							A0709	Device Sensing Problem	22/02/2024	22/02/2024		
6489	2024	All other reportable incidents			CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A04	Material Integrity Problem	22/02/2024	22/02/2024
									A0709	Device Sensing Problem	22/02/2024	22/02/2024
									A070909	Oversensing	22/02/2024	22/02/2024
									A04	Material Integrity Problem	22/02/2024	22/02/2024
									A0709	Device Sensing Problem	22/02/2024	22/02/2024
									A070909	Oversensing	22/02/2024	22/02/2024
							F1905	Device Revision or Replacement	A04	Material Integrity Problem	22/02/2024	22/02/2024
									A0709	Device Sensing Problem	22/02/2024	22/02/2024
									A070909	Oversensing	22/02/2024	22/02/2024
									A04	Material Integrity Problem	22/02/2024	22/02/2024
									A0709	Device Sensing Problem	22/02/2024	22/02/2024
									A070909	Oversensing	22/02/2024	22/02/2024
F2203	imaging Required	A04	Material Integrity Problem	22/02/2024	22/02/2024							
		A0709	Device Sensing Problem	22/02/2024	22/02/2024							
		A070909	Oversensing	22/02/2024	22/02/2024							
		A04	Material Integrity Problem	22/02/2024	22/02/2024							
		A0709	Device Sensing Problem	22/02/2024	22/02/2024							
		A070909	Oversensing	22/02/2024	22/02/2024							

6489	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	24/09/2024	24/09/2024
									A1206	Misconnection	24/09/2024	24/09/2024
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem	24/09/2024	24/09/2024
									A1206	Misconnection	24/09/2024	24/09/2024

6490	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
							A0709	Device Sensing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
							A0709	Device Sensing Problem				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
		A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
		A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
		A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
		A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A0709	Device Sensing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A0709	Device Sensing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A0709	Device Sensing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
				A0709	Device Sensing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
		A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									
		A0709	Device Sensing Problem									
		A071302	Inappropriate/Inadequate Shock/Stimulation									

6491	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		

6492	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		

					CT258	Implantable defibrillators	F1901	Additional Surgery	A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	F1901	Additional Surgery	A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
6493	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	F1901	Additional Surgery	A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
6494	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6495	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
6496	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0112	Dizziness	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							E233001	Chest Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		

							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E0112	Dizziness	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							E233001	Chest Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2666	Implantable cardiac electrical stimulators	E0112	Dizziness	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E233001	Chest Pain	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8497	2024	Death	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
									A090811	Unable to Obtain Readings		
							F02	Death	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
									A090811	Unable to Obtain Readings		
8498	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2666	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8499	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
					CT2666	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/12/2024	19/12/2024
8500	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
									A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
									A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
					CT2666	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/10/2024	28/10/2024
8501	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024

					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
									A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
							F1903	Device Explanation	A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
									A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
									A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
							F1903	Device Explanation	A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
8502	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	23/09/2024	23/09/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	23/09/2024	23/09/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	23/09/2024	23/09/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	23/09/2024	23/09/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	23/09/2024	23/09/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	23/09/2024	23/09/2024
8503	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2024	04/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
									A0705	Battery Problem	04/10/2024	04/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
									A0705	Battery Problem	04/10/2024	04/10/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/10/2024	04/10/2024
									A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2024	04/10/2024
									A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2024	04/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
									A0705	Battery Problem	04/10/2024	04/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
									A0705	Battery Problem	04/10/2024	04/10/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/10/2024	04/10/2024
									A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/10/2024	04/10/2024
									A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2024	04/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
									A0705	Battery Problem	04/10/2024	04/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
									A0705	Battery Problem	04/10/2024	04/10/2024
8504	2024		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2024	04/10/2024
							F1901	Additional Surgery	A25	No Apparent Adverse Event	07/10/2024	07/10/2024
8505	2024		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E06	Heart	A0714	Unintended Electrical Shock	07/10/2024	07/10/2024
							F05	Delay to Treatment/ Therapy	A0714	Unintended Electrical Shock	07/10/2024	07/10/2024
8506	2024		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070603	Failure to Charge	07/10/2024	07/10/2024
									A071302	It's appropriate/inadequate Shock/Stimulation	07/10/2024	07/10/2024
							F1901	Additional Surgery	A070603	Failure to Charge	07/10/2024	07/10/2024
									A071302	Inappropriate/inadequate Shock/Stimulation	07/10/2024	07/10/2024
8507	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8508	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8509	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F13	Misdiagnosis/ Misclassification	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
8510	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8511	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8512	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A071204	No Pacing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
									A071204	No Pacing		
8513	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0112	Dizziness	A0709	Device Sensing Problem		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							E011902	Presyncope	A0709	Device Sensing Problem		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		

								A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT1150	Defibrillators	E0112	Dizziness	A0709	Device Sensing Problem	
							E011902	Presyncope	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F12	Serious Injury/ Illness/ Impairment	A071302	Device Sensing Problem	
							F2307	Reprogramming of Device	A0709	Device Sensing Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT258	Implantable defibrillators	E0112	Dizziness	A0709	Device Sensing Problem	
							E011902	Presyncope	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem	
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation	
									A0709	Device Sensing Problem	
					CT263	Cardiographs and associated devices	E0112	Dizziness	A071302	Inappropriate/Inadequate Shock/Stimulation	
							E011902	Presyncope	A0709	Device Sensing Problem	
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F2307	Reprogramming of Device	A0709	Device Sensing Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
					CT2866	Implantable cardiac electrical stimulators	E0112	Dizziness	A0709	Device Sensing Problem	
							E011902	Presyncope	A071302	Inappropriate/Inadequate Shock/Stimulation	
							F12	Serious Injury/ Illness/ Impairment	A071302	Device Sensing Problem	
							F2307	Reprogramming of Device	A0709	Device Sensing Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation	
6514	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	07/10/2024
							F1901	Additional Surgery	A070603	Failure to Charge	07/10/2024
6515	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
6516	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
									A072001	Electromagnetic Interference	
									A090801	Signal Artifact/Noise	
									A090811	Unable to Obtain Readings	
						F12	Serious Injury/ Illness/ Impairment		A070909	Oversensing	
									A072001	Electromagnetic Interference	
									A090801	Signal Artifact/Noise	
									A090811	Unable to Obtain Readings	
						F2307	Reprogramming of Device		A070909	Oversensing	
									A072001	Electromagnetic Interference	
									A090801	Signal Artifact/Noise	
									A090811	Unable to Obtain Readings	
6517	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/11/2024
									A070504	Premature Discharge of Battery	05/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/11/2024
						F1903	Device Explanation		A070504	Premature Discharge of Battery	05/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/11/2024
6518	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/12/2024
									A070504	Premature Discharge of Battery	05/12/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/12/2024
						F08	Hospitalization or Prolonged Hospitalization		A0705	Battery Problem	05/12/2024
									A070504	Premature Discharge of Battery	05/12/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/12/2024
						F1905	Device Revision or Replacement		A0705	Battery Problem	05/12/2024
									A070504	Premature Discharge of Battery	05/12/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/12/2024
6519	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070504	Premature Discharge of Battery	15/12/2024
									A070909	Oversensing	15/12/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	15/12/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/12/2024
									A090801	Signal Artifact/Noise	15/12/2024
									A150202	Malposition of Device	15/12/2024
						F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	15/12/2024
									A070909	Oversensing	15/12/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	15/12/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/12/2024
									A090801	Signal Artifact/Noise	15/12/2024
									A150202	Malposition of Device	15/12/2024
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070504	Premature Discharge of Battery	15/12/2024
									A070909	Oversensing	15/12/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	15/12/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/12/2024
									A090801	Signal Artifact/Noise	15/12/2024
									A150202	Malposition of Device	15/12/2024
						F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	15/12/2024

							A070909	Oversensing	15/12/2024	15/12/2024
							A071302	Inappropriate/inadequate Shock/Stimulation	15/12/2024	15/12/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/12/2024	15/12/2024
							A090801	Signal Artifact/Noise	15/12/2024	15/12/2024
						F2203	A150202	Malposition of Device	15/12/2024	15/12/2024
							A070504	Premature Discharge of Battery	15/12/2024	15/12/2024
							A070909	Oversensing	15/12/2024	15/12/2024
							A071302	Inappropriate/inadequate Shock/Stimulation	15/12/2024	15/12/2024
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/12/2024	15/12/2024
							A090801	Signal Artifact/Noise	15/12/2024	15/12/2024
							A150202	Malposition of Device	15/12/2024	15/12/2024
6520	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing
									A071204	No Pacing
									A071302	Inappropriate/inadequate Shock/Stimulation
						F12	A070909	Serious Injury/ Illness/ Impairment	Oversensing	
							A071204	No Pacing		
							A071302	Inappropriate/inadequate Shock/Stimulation		
6521	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery
									A0908	Incorrect, Inadequate or Imprecise Result or Readings
						F08	A070504	Hospitalization or Prolonged Hospitalization	Premature Discharge of Battery	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F1905	A070504	Device Revision or Replacement	Premature Discharge of Battery	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings		
6522	2024		37265	Dual-chamber implantable defibrillator	C11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
							A0705	Device Revision or Replacement	Battery Problem	
						F23	A0705	Unexpected Medical Intervention	Battery Problem	
					C1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
						F1905	A0705	Device Revision or Replacement	Battery Problem	
						F23	A0705	Unexpected Medical Intervention	Battery Problem	
					C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
						F1905	A0705	Device Revision or Replacement	Battery Problem	
						F23	A0705	Unexpected Medical Intervention	Battery Problem	
6523	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	C11150	Defibrillators	E060109	Tachycardia	A0713	Defibrillation/Stimulation Problem
									A0722	Impedance Problem
									A072202	Low Impedance
						E0602	A0713	Cardiac Arrest	Defibrillation/Stimulation Problem	
							A0722	Impedance Problem		
							A072202	Low Impedance		
						F08	A0713	Hospitalization or Prolonged Hospitalization	Defibrillation/Stimulation Problem	
							A0722	Impedance Problem		
							A072202	Low Impedance		
						F0801	A0713	Intensive Care	Defibrillation/Stimulation Problem	
							A0722	Impedance Problem		
							A072202	Low Impedance		
						F1203	A0713	Life Threatening Illness or Injury	Defibrillation/Stimulation Problem	
							A0722	Impedance Problem		
							A072202	Low Impedance		
						F1905	A0713	Device Revision or Replacement	Defibrillation/Stimulation Problem	
							A0722	Impedance Problem		
							A072202	Low Impedance		
						F2306	A0713	Resuscitation	Defibrillation/Stimulation Problem	
							A0722	Impedance Problem		
							A072202	Low Impedance		
						F2307	A0713	Reprogramming of Device	Defibrillation/Stimulation Problem	
							A0722	Impedance Problem		
							A072202	Low Impedance		
					C1258	Implantable defibrillators	E060109	Tachycardia	A0713	Defibr

							F0801	Intensive Care	A0713	Defibrillation/Stimulation Problem	17/10/2024	17/10/2024
									A0722	Impedance Problem	17/10/2024	17/10/2024
							F1203	Life Threatening Illness or Injury	A072202	Low Impedance	17/10/2024	17/10/2024
									A0713	Defibrillation/Stimulation Problem	17/10/2024	17/10/2024
									A0722	Impedance Problem	17/10/2024	17/10/2024
									A072202	Low Impedance	17/10/2024	17/10/2024
							F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem	17/10/2024	17/10/2024
									A0722	Impedance Problem	17/10/2024	17/10/2024
									A072202	Low Impedance	17/10/2024	17/10/2024
							F2306	Resuscitation	A0713	Defibrillation/Stimulation Problem	17/10/2024	17/10/2024
									A0722	Impedance Problem	17/10/2024	17/10/2024
									A072202	Low Impedance	17/10/2024	17/10/2024
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem	17/10/2024	17/10/2024
									A0722	Impedance Problem	17/10/2024	17/10/2024
									A072202	Low Impedance	17/10/2024	17/10/2024
8524	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
8525	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A07			

								Exposure	A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
									A070910	Undersensing		
6536	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6537	2024	Unanticipated serious deterioration in state of health	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0610	Endocarditis	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							E062104	Tricuspid Valve Insufficiency/ Regurgitation	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							E1901	Bacterial Infection	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F1903	Device Explanation	A24	No Apparent Device Problem	17/10/2024	17/10/2024
					CT258	Implantable defibrillators	E0610	Endocarditis	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							E062104	Tricuspid Valve Insufficiency/ Regurgitation	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							E1901	Bacterial Infection	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F1903	Device Explanation	A24	No Apparent Device Problem	17/10/2024	17/10/2024
					CT2866	Implantable cardiac electrical stimulators	E0610	Endocarditis	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							E062104	Tricuspid Valve Insufficiency/ Regurgitation	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							E1901	Bacterial Infection	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	17/10/2024	17/10/2024
							F1903	Device Explanation	A24	No Apparent Device Problem	17/10/2024	17/10/2024
6538	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A0722	Impedance Problem		
									A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact	A05	Mechanical Problem			
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A0722	Impedance Problem		
									A072201	High Impedance		
									A072202	Low Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A0722	Impedance Problem		
									A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact	A05	Mechanical Problem			
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A0722	Impedance Problem		
									A072201	High Impedance		
									A072202	Low Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A0722	Impedance Problem		
									A072201	High Impedance		
									A072202	Low Impedance		
						F26	No Health Consequences or Impact	A05	Mechanical Problem			
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A0722	Impedance Problem		
									A072201	High Impedance		
									A072202	Low Impedance		
6539	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
6540	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
						F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A0712	Pacing Problem		

					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801 A0709 A070909 A0712 A090801 A0709 A070909 A0712 A090801	Signal Artifact/Noise Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise Device Sensing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A0712 A090801	Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise			
							F12	Serious Injury/ Illness/ Impairment	A0709 A070909 A0712 A090801	Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise			
							F2307	Reprogramming of Device	A0709 A070909 A0712 A090801	Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909 A0712 A090801	Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A0712 A090801	Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise			
							F12	Serious Injury/ Illness/ Impairment	A0709 A070909 A0712 A090801	Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise			
							F2307	Reprogramming of Device	A0709 A070909 A0712 A090801	Device Sensing Problem Oversensing Pacing Problem Signal Artifact/Noise			
6541	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation	16/12/2024 16/12/2024 16/12/2024 16/12/2024	16/12/2024 16/12/2024 16/12/2024 16/12/2024	
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	16/12/2024 16/12/2024	16/12/2024 16/12/2024	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	16/12/2024 16/12/2024	16/12/2024 16/12/2024	
							F1905	Device Revision or Replacement	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	16/12/2024 16/12/2024	16/12/2024 16/12/2024	
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	16/12/2024 16/12/2024	16/12/2024 16/12/2024	
6542	2024	All other reportable incidents			CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909 A071302 A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation			
6543	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	22/01/2025 22/01/2025 22/01/2025 22/01/2025	22/01/2025 22/01/2025 22/01/2025 22/01/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	22/01/2025 22/01/2025	22/01/2025 22/01/2025	
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	22/01/2025 22/01/2025	22/01/2025 22/01/2025	
6544	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	04/06/2025 04/06/2025 04/06/2025 04/06/2025	04/06/2025 04/06/2025 04/06/2025 04/06/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	04/06/2025 04/06/2025	04/06/2025 04/06/2025	
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	04/06/2025 04/06/2025	04/06/2025 04/06/2025	
6545	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0712 A071302 A1301 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0712 A071302 A1301 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal			
6546	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070909 A070909 A070909	Oversensing Oversensing Oversensing Oversensing			
6547	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072201 A072201	Oversensing High Impedance High Impedance			
6548	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			

							E2403	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						CT258	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						CT2866	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
6549	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F1905	Device Revision or Replacement	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F2203	Imaging Required	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F1905	Device Revision or Replacement	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F2203	Imaging Required	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102 A070909 A071302 A0908 A090801	High Capture Threshold Oversensing Inappropriate/Inadequate Shock/Stimulation Incorrect, Inadequate or Imprecise Result or Readings Signal Artifact/Noise	08/11/2024 08/11/2024 08/11/2024 08/11/2024 08/11/2024	08/1

									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070102	High Capture Threshold	08/11/2024	08/11/2024
									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
						F1905	Device Revision or Replacement		A070102	High Capture Threshold	08/11/2024	08/11/2024
									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
						F2203	Imaging Required		A070102	High Capture Threshold	08/11/2024	08/11/2024
									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070102	High Capture Threshold	08/11/2024	08/11/2024
									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
						F08	Hospitalization or Prolonged Hospitalization		A070102	High Capture Threshold	08/11/2024	08/11/2024
									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070102	High Capture Threshold	08/11/2024	08/11/2024
									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
						F1905	Device Revision or Replacement		A070102	High Capture Threshold	08/11/2024	08/11/2024
									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
						F2203	Imaging Required		A070102	High Capture Threshold	08/11/2024	08/11/2024
									A070909	Oversensing	08/11/2024	08/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	08/11/2024	08/11/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	08/11/2024	08/11/2024
									A090801	Signal Artifact/Noise	08/11/2024	08/11/2024
8551	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/01/2025	07/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/01/2025	07/01/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/01/2025	07/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/01/2025	07/01/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/01/2025	07/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/01/2025	07/01/2025
8552	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F2203	Imaging Required		A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
8553	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8554	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	11/10/2024	11/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	11/10/2024	11/10/2024
							F1905	Device Revision or Replacement	A070909	Oversensing	11/10/2024	11/10/2024
8555	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
8556	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
									A070909	Oversensing		
									A071201	Failure to Convert Rhythm		
8557	2024	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/10/2024	17/10/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2024	17/10/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/10/2024	17/10/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2024	17/10/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/10/2024	17/10/2024

8558	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070908	Incorrect, Inadequate or Imprecise Result or Readings	17/10/2024	17/10/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
									A070909	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Oversensing		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
									A070909	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Oversensing		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
									A070909	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8559	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
8560	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
8561	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/01/2025	23/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/01/2025	23/01/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/01/2025	23/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/01/2025	23/01/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/01/2025	23/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/01/2025	23/01/2025
8562	2024	Unanticipated serious deterioration in state of health	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
8563	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/01/2025	06/01/2025
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	06/01/2025	06/01/2025
8564	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	01/11/2024	01/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A05	Mechanical Problem	01/11/2024	01/11/2024
							F12	Serious Injury/Illness/ Impairment	A05	Mechanical Problem	01/11/2024	01/11/2024
							F1905	Device Revision or Replacement	A05	Mechanical Problem	01/11/2024	01/11/2024
8565	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8566	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
8567	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F12	Serious Injury/Illness/ Impairment	A160503	Inappropriate or Unexpected Reset		
									A1605	Reset Problem		
							F2307	Reprogramming of Device	A160503	Inappropriate or Unexpected Reset		
									A1605	Reset Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset		
							F12	Serious Injury/Illness/ Impairment	A1605	Reset Problem		
									A160503	Inappropriate or Unexpected Reset		
							F2307	Reprogramming of Device	A1605	Reset Problem		
									A160503	Inappropriate or Unexpected Reset		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F12	Serious Injury/Illness/ Impairment	A160503	Inappropriate or Unexpected Reset		
									A1605	Reset Problem		
									A160503	Inappropriate or Unexpected Reset		

							F2307	Reprogramming of Device	A1605	Reset Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset		
							F12	Serious Injury/ Illness/ Impairment	A1605	Reset Problem		
							F2307	Reprogramming of Device	A160503	Inappropriate or Unexpected Reset		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F12	Serious Injury/ Illness/ Impairment	A160503	Inappropriate or Unexpected Reset		
							F2307	Reprogramming of Device	A1605	Reset Problem		
8568	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/11/2024	18/11/2024
8569	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/01/2025	30/01/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/01/2025	30/01/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/01/2025	30/01/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/01/2025	30/01/2025
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/01/2025	30/01/2025
8570	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/11/2024	07/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/11/2024	07/11/2024
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	07/11/2024	07/11/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	07/11/2024	07/11/2024
8571	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
8572	2024	Death	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A24	No Apparent Device Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A24	No Apparent Device Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A24	No Apparent Device Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A24	No Apparent Device Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A24	No Apparent Device Problem		
8573	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/11/2024	04/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2024	04/11/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2024	04/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2024	04/11/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2024	04/11/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2024	04/11/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/11/2024	04/11/2024
							F1905	Device Revision or Replacement	A0705	Battery Problem	04/11/2024	04/11/2024
8574	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
8575	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024

							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/11/2024	25/11/2024
6576	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A090402	Failure to Deliver Energy		
							F28	Appropriate Health Impact Term/Code not Available	A090402	Insufficient Device Problem Information		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090402	Failure to Deliver Energy		
							F28	Appropriate Health Impact Term/Code not Available	A090402	Insufficient Device Problem Information		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090402	Failure to Deliver Energy		
							F28	Appropriate Health Impact Term/Code not Available	A090402	Insufficient Device Problem Information		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090402	Failure to Deliver Energy		
							F28	Appropriate Health Impact Term/Code not Available	A090402	Insufficient Device Problem Information		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090402	Failure to Deliver Energy		
							F28	Appropriate Health Impact Term/Code not Available	A090402	Insufficient Device Problem Information		
6577	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
6578	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
6579	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2024	19/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2024	19/11/2024
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	19/11/2024	19/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/11/2024	19/11/2024
6580	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025

							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
					CT1150	Defibrillators	F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F1905	Device Revision or Replacement	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F1905	Device Revision or Replacement	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2025	03/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
8561	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	03/02/2025	03/02/2025
							F26	No Health Consequences or Impact	A072201	Data Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	Data Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	Data Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	Data Problem		
8562	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2024	31/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/01/2024	31/12/2024
							F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	01/01/2024	31/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/01/2024	31/12/2024
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	01/01/2024	31/12/2024
8583	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	19/11/2024	19/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0711	Interrogation Problem	19/11/2024	19/11/2024
							F1905	Device Revision or Replacement	A0711	Interrogation Problem	19/11/2024	19/11/2024
8584	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	03/02/2025	03/02/2025
8585	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8586	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F08	Hospitalization or Prolonged Hospitalization	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
							F1905	Device Revision or Replacement	A1304	Telemetry Discrepancy	19/10/2023	19/10/2023
8587	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/02/2025	28/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/02/2025	28/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/02/2025	28/02/2025
8588	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A0709	Device Sensing Problem		

							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A0709	Device Sensing Problem		
8589	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8590	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A05	Mechanical Problem		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A05	Mechanical Problem		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A05	Mechanical Problem		
									A072201	High Impedance		
8591	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070912	Incorrect Interpretation of Signal		
									A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8592	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	26/11/2024	26/11/2024
8593	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

8594	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery																							
					E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery																									
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery																									
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery																							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery																									
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery																							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery																									
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery																							
					F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery																									
					CT1150	Defibrillators	E0601	Arrhythmia	A24	No Apparent Device Problem	06/11/2024	06/11/2024																					
							E1901	Bacterial Infection	A24	No Apparent Device Problem	06/11/2024	06/11/2024																					
							F02	Death	A24	No Apparent Device Problem	06/11/2024	06/11/2024																					
						Implantable defibrillators	E0601	Arrhythmia	A24	No Apparent Device Problem	06/11/2024	06/11/2024																					
							E1901	Bacterial Infection	A24	No Apparent Device Problem	06/11/2024	06/11/2024																					
							F02	Death	A24	No Apparent Device Problem	06/11/2024	06/11/2024																					
CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A24	No Apparent Device Problem	06/11/2024	06/11/2024																										
		E1901	Bacterial Infection	A24	No Apparent Device Problem	06/11/2024	06/11/2024																										
		F02	Death	A24	No Apparent Device Problem	06/11/2024	06/11/2024																										
8595	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing																							
							Undersensing	A070910	Undersensing																								
							Undersensing	A071302	Inappropriate/Inadequate Shock/Stimulation																								
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing																							
									A070910	Undersensing																							
									A071302	Inappropriate/Inadequate Shock/Stimulation																							
							F2203	Imaging Required	A070909	Oversensing																							
									A070910	Undersensing																							
									A071302	Inappropriate/Inadequate Shock/Stimulation																							
							8596	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture	15/11/2024	15/11/2024														
														F08	Hospitalization or Prolonged Hospitalization	A040101	Fracture	15/11/2024	15/11/2024														
														F1905	Device Revision or Replacement	A040101	Fracture	15/11/2024	15/11/2024														
														8597	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem									
																					Undersensing	A071302	Inappropriate/Inadequate Shock/Stimulation										
																					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem									
A071302	Inappropriate/Inadequate Shock/Stimulation																																
A0712	Pacing Problem																																
F2303	Medication Required	A0712	Pacing Problem																														
A071302	Inappropriate/Inadequate Shock/Stimulation																																
8598	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators															E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/09/2024	01/09/2024							
																					F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/09/2024	01/09/2024							
																					F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/09/2024	01/09/2024							
																					8599	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
																												A072001	Electromagnetic Interference				
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem																							
							A072001	Electromagnetic Interference																									
							F2307	Reprogramming of Device	A0709	Device Sensing Problem																							
									A072001	Electromagnetic Interference																							
									A072001	Electromagnetic Interference																							
									A072001	Electromagnetic Interference																							
									A072001	Electromagnetic Interference																							
									A072001	Electromagnetic Interference																							
							8600	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance																
														F26	No Health Consequences or Impact	A072201	High Impedance																
A072201	High Impedance																																
8601	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices								E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	22/09/2024	22/09/2024														
														F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2024	22/09/2024														
																A13	Communication or Transmission Problem	22/09/2024	22/09/2024														
																A0508	Noise, Audible	22/09/2024	22/09/2024														
														F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2024	22/09/2024														
																A13	Communication or Transmission Problem	22/09/2024	22/09/2024														
																A0508	Noise, Audible	22/09/2024	22/09/2024														
														CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	22/09/2024	22/09/2024												
																F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2024	22/09/2024												
																		A13	Communication or Transmission Problem	22/09/2024	22/09/2024												
														F1905	Device Revision or Replacement			A070504	Premature Discharge of Battery	22/09/2024	22/09/2024												
																A13	Communication or Transmission Problem	22/09/2024	22/09/2024														
							A0508	Noise, Audible	22/09/2024	22/09/2024																							
							CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	22/09/2024	22/09/2024																			
									F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2024	22/09/2024																			
A13	Communication or Transmission Problem	22/09/2024	22/09/2024																														
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	22/09/2024	22/09/2024																												
		A13	Communication or Transmission Problem	22/09/2024	22/09/2024																												
		A0508	Noise, Audible	22/09/2024	22/09/2024																												
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	22/09/2024	22/09/2024																										
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2024	22/09/2024																										
				A13	Communication or Transmission Problem	22/09/2024	22/09/2024																										
F1905	Device Revision or Replacement			A0508	Noise, Audible	22/09/2024	22/09/2024																										
		A070504	Premature Discharge of Battery	22/09/2024	22/09/2024																												
		A13	Communication or Transmission Problem	22/09/2024	22/09/2024																												
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible	22/09/2024	22/09/2024																										
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	22/09/2024	22/09/2024																										
				A13	Communication or Transmission Problem	22/09/2024	22/09/2024																										

							F1905	Device Revision or Replacement	A0508	Noise, Audible	22/09/2024	22/09/2024
									A070504	Premature Discharge of Battery	22/09/2024	22/09/2024
									A13	Communication or Transmission Problem	22/09/2024	22/09/2024
8602	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8603	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A0709	Device Sensing Problem	29/11/2024	29/11/2024
							F02	Death	A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
					CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem	29/11/2024	29/11/2024
							F02	Death	A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
					CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem	29/11/2024	29/11/2024
							F02	Death	A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
					CT263	Cardiographs and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem	29/11/2024	29/11/2024
							F02	Death	A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem	29/11/2024	29/11/2024
							F02	Death	A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	29/11/2024	29/11/2024
									A071301	Failure to Deliver Shock/Stimulation	29/11/2024	29/11/2024
8604	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/11/2024	29/11/2024
8605	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
8606	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060104	Bradycardia	A070909	Oversensing		
									A0712	Pacing Problem		
							F1001	Absence of Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
							F2203	Imaging Required	A070909	Oversensing		
									A0712	Pacing Problem		
8607	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/10/2024	15/10/2024
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	15/10/2024	15/10/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/10/2024	15/10/2024
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	15/10/2024	15/10/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/10/2024	15/10/2024
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	15/10/2024	15/10/2024
8608	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Itappropriate/inadequate Shock/Stimulation		
8609	2024		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
8610	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060104	Bradycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E060104	Bradycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060104	Bradycardia	A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
8611	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/ Illness/ Impairment	A070912	Incorrect Interpretation of Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070912	Incorrect Interpretation of Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070912	Incorrect Interpretation of Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/ Illness/ Impairment	A070912	Incorrect Interpretation of Signal		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070912	Incorrect Interpretation of Signal		
8612	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A150202	Malposition of Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A150202	Malposition of Device		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A150202	Malposition of Device		
8613	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
8614	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/01/2025	28/01/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
8615	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		

							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
									A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
8616	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/03/2025	01/03/2025
									A0722	Impedance Problem	01/03/2025	01/03/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/03/2025	01/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/03/2025	01/03/2025
									A0722	Impedance Problem	01/03/2025	01/03/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/03/2025	01/03/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	01/03/2025	01/03/2025
									A0722	Impedance Problem	01/03/2025	01/03/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/03/2025	01/03/2025
8617	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F2203	Imaging Required	A072202	Low Impedance		
8618	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							CT2866	Implantable cardiac electrical stimulators	A160601	Premature Elective Replacement Indicator		
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
8619	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8620	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
									A051201	Device Dislodged or Dislocated		
							F26	No Health Consequences or Impact	A010402	Migration		
									A051201	Device Dislodged or Dislocated		
8621	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	09/12/2024	09/12/2024
									A072201	High Impedance	09/12/2024	09/12/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	09/12/2024	09/12/2024
									A072201	High Impedance	09/12/2024	09/12/2024
8622	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/03/2025	26/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/03/2025	26/03/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/03/2025	26/03/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	26/03/2025	26/03/2025
8623	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
8624	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/09/2025	17/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/09/2025	17/09/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	17/09/2025	17/09/2025
8625	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							CT1150	Defibrillators	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
									A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							CT258	Implantable defibrillators	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
									A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							CT263	Cardiographs and associated devices	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							CT2866	Implantable cardiac electrical stimulators	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator	12/12/2024	12/12/2024
8626	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0138	Undesired Nerve Stimulation	A0101	Patient-Device Incompatibility		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F22	Unexpected Diagnostic Intervention	A0101	Patient-Device Incompatibility		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2306	Resuscitation	A0101	Patient-Device Incompatibility		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
8627	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8628	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							CT258	Implantable defibrillators	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							CT263	Cardiographs and associated devices	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							CT2866	implantable cardiac electrical stimulators	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8629	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	16/12/2024	16/12/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	16/12/2024	16/12/2024
							CT258	Implantable defibrillators	A05	Mechanical Problem	16/12/2024	16/12/2024
									A05	Mechanical Problem	16/12/2024	16/12/2024
							CT2866	Implantable cardiac electrical stimulators	A05	Mechanical Problem	16/12/2024	16/12/2024
							F26	No Health Consequences or Impact	A05	Mechanical Problem	16/12/2024	16/12/2024
8630	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		

					CT1150	Defibrillators	E210401	Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070908	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
								Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
6636	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
6637	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/01/2025	20/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/01/2025	20/01/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/01/2025	20/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/01/2025	20/01/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/01/2025	20/01/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/01/2025	20/01/2025
6638	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A090812	Missing Test Results	20/12/2024	20/12/2024
							F27	Problem Identified During Non-Clinical Procedure	A090812	Missing Test Results	20/12/2024	20/12/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090812	Missing Test Results	20/12/2024	20/12/2024
							F27	Problem Identified During Non-Clinical Procedure	A090812	Missing Test Results	20/12/2024	20/12/2024
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090812	Missing Test Results	20/12/2024	20/12/2024
							F27	Problem Identified During Non-Clinical Procedure	A090812	Missing Test Results	20/12/2024	20/12/2024
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090812	Missing Test Results	20/12/2024	20/12/2024
							F27	Problem Identified During Non-Clinical Procedure	A090812	Missing Test Results	20/12/2024	20/12/2024
					CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090812	Missing Test Results	20/12/2024	20/12/2024
							F27	Problem Identified During Non-Clinical Procedure	A090812	Missing Test Results	20/12/2024	20/12/2024
6639	2024	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
6640	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
									A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
6641	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/01/2025	08/01/2025
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator	08/01/2025	08/01/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
6642	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A072201	High Impedance		
							F17	Swallow	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
6643	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060101	Ayctyle	A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		

							F1001	Absence of Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E060101	Asystole	A070909	Oversensing		
									A0712	Pacing Problem		
							F1001	Absence of Treatment	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060101	Asystole	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A0712	Pacing Problem		
							F1001	Absence of Treatment	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A0712	Pacing Problem		
8644	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F22	Unexpected Diagnostic Intervention	A071204	No Pacing		
									A070909	Oversensing		
8645	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	27/12/2024	27/12/2024
8646	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8647	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	Tachycardia	A0712	Pacing Problem		
							E060110	Ventricular Fibrillation	A0712	Pacing Problem		
							E1610	Head Injury	A0712	Pacing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
							F2303	Medication Required	A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E060109	Tachycardia	A0712	Pacing Problem		
							E060110	Ventricular Fibrillation	A0712	Pacing Problem		
							E1610	Head Injury	A0712	Pacing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
							F2303	Medication Required	A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0712	Pacing Problem		

								E060110	Ventricular Fibrillation	A0712	Pacing Problem		
								E1610	Head Injury	A0712	Pacing Problem		
								F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem		
								F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
								F2303	Medication Required	A0712	Pacing Problem		
								F2307	Reprogramming of Device	A0712	Pacing Problem		
6648	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/02/2025	05/02/2025
										A070504	Premature Discharge of Battery	05/02/2025	05/02/2025
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/02/2025	05/02/2025
										A070504	Premature Discharge of Battery	05/02/2025	05/02/2025
								F1905	Device Revision or Replacement	A0705	Battery Problem	05/02/2025	05/02/2025
										A070504	Premature Discharge of Battery	05/02/2025	05/02/2025
6649	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/12/2024	23/12/2024
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/12/2024	23/12/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2024	23/12/2024
6650	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators		E210401	Shock from Patient Lead(s)	A070909	Oversensing	20/02/2025	20/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	20/02/2025	20/02/2025
								F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	20/02/2025	20/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	20/02/2025	20/02/2025
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	20/02/2025	20/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	20/02/2025	20/02/2025
								F1905	Device Revision or Replacement	A070909	Oversensing	20/02/2025	20/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	20/02/2025	20/02/2025
								F23	Unexpected Medical Intervention	A070909	Oversensing	20/02/2025	20/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	20/02/2025	20/02/2025
6651	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators		E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
6652	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0712	Pacing Problem		
6653	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070102	High Capture Threshold		
										A0705	Battery Problem		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070102	High Capture Threshold		
										A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
										A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070102	High Capture Threshold		
										A0705	Battery Problem		
6654	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F24	Insufficient Health Impact Information	A0705	Battery Problem		
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
										A0705	Battery Problem		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
										A0705	Battery Problem		
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
										A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
										A0705	Battery Problem		
6655	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
								F1905	Device Revision or Replacement	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
								F1905	Device Revision or Replacement	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
								F1905	Device Revision or Replacement	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	29/10/2024	29/10/2024
										A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
										A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
								F1905	Device Revision or Replacement	A0705	Battery Problem	29/10/2024	29/10/2024

									A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
					C12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	29/10/2024	29/10/2024
									A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
						F08	Hospitalization or Prolonged Hospitalization		A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
									A0705	Battery Problem	29/10/2024	29/10/2024
									A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
						F1905	Device Revision or Replacement		A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
									A0705	Battery Problem	29/10/2024	29/10/2024
									A070504	Premature Discharge of Battery	29/10/2024	29/10/2024
									A1304	Telemetry Discrepancy	29/10/2024	29/10/2024
6656	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	C1258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	06/05/2025	06/05/2025
									A070504	Premature Discharge of Battery	06/05/2025	06/05/2025
						F08	Hospitalization or Prolonged Hospitalization		A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/05/2025	06/05/2025
									A0705	Battery Problem	06/05/2025	06/05/2025
									A070504	Premature Discharge of Battery	06/05/2025	06/05/2025
						F1905	Device Revision or Replacement		A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/05/2025	06/05/2025
									A0705	Battery Problem	06/05/2025	06/05/2025
									A070504	Premature Discharge of Battery	06/05/2025	06/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	06/05/2025	06/05/2025
6657	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
						F1203	Life Threatening Illness or Injury		A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
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									A071302	Inappropriate/Inadequate Shock/Stimulation		
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									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
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									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		

6667	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F2203	Imaging Required	A040191	Fracture									
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
									A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
									A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
									A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
									A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
									A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
									A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
									A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
				A070504	Premature Discharge of Battery	10/03/2025	10/03/2025												
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025												
6668	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/03/2025	10/03/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/03/2025	10/03/2025							
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/04/2025	29/04/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/04/2025	29/04/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/04/2025	29/04/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/04/2025	29/04/2025							
									A070504	Premature Discharge of Battery	29/04/2025	29/04/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/04/2025	29/04/2025							
									A070504	Premature Discharge of Battery	29/04/2025	29/04/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/04/2025	29/04/2025							
									A070504	Premature Discharge of Battery	29/04/2025	29/04/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	29/04/2025	29/04/2025							
6669	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery							
							F26		No Health Consequences or Impact	A070504	Premature Discharge of Battery								
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
							6670	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0705	Battery Problem	01/01/2025	31/01/2025
																A0709	Device Sensing Problem	01/01/2025	31/01/2025
					F08	Hospitalization or Prolonged Hospitalization								A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025		
															A0705	Battery Problem	01/01/2025	31/01/2025	
								A0709	Device Sensing Problem	01/01/2025	31/01/2025								
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025								
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	01/01/2025	31/01/2025												
		A0709		Device Sensing Problem	01/01/2025	31/01/2025													
		A071302		Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025													
		A0705		Battery Problem	01/01/2025	31/01/2025													
		F1203	Life Threatening Illness or Injury	A0705	Battery Problem	01/01/2025	31/01/2025												
		A0709		Device Sensing Problem	01/01/2025	31/01/2025													
		A071302		Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025													
		A0705		Battery Problem	01/01/2025	31/01/2025													
		F1905	Device Revision or Replacement	A0705	Battery Problem	01/01/2025	31/01/2025												
		A0709		Device Sensing Problem	01/01/2025	31/01/2025													
		A071302		Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025													
		A0705		Battery Problem	01/01/2025	31/01/2025													
6670	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0705	Battery Problem	01/01/2025			31/01/2025					
									A0709	Device Sensing Problem	01/01/2025			31/01/2025					
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025			31/01/2025					
										A0705	Battery Problem			01/01/2025	31/01/2025				
										A0709	Device Sensing Problem			01/01/2025	31/01/2025				
										A071302	Inappropriate/Inadequate Shock/Stimulation			01/01/2025	31/01/2025				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705	Battery Problem	01/01/2025	31/01/2025					
									A0709		Device Sensing Problem	01/01/2025	31/01/2025						
									A071302		Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025						
									A0705		Battery Problem	01/01/2025	31/01/2025						
									F1203	Life Threatening Illness or Injury	A0705	Battery Problem	01/01/2025	31/01/2025					
									A0709		Device Sensing Problem	01/01/2025	31/01/2025						
							A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025		31/01/2025								
							A0705	Battery Problem	01/01/2025		31/01/2025								
							F1905	Device Revision or Replacement	A0705	Battery Problem	01/01/2025	31/01/2025							
							A0709		Device Sensing Problem	01/01/2025	31/01/2025								
							A071302		Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025								
							A0705		Battery Problem	01/01/2025	31/01/2025								
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0705	Battery Problem	01/01/2025	31/01/2025							
									A0709	Device Sensing Problem	01/01/2025	31/01/2025							
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025							
										A0705	Battery Problem	01/01/2025	31/01/2025						
										A0709	Device Sensing Problem	01/01/2025	31/01/2025						
										A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025						
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705			Battery Problem	01/01/2025	31/01/2025										
		A0709		Device Sensing Problem			01/01/2025	31/01/2025											
		A071302		Inappropriate/Inadequate Shock/Stimulation			01/01/2025	31/01/2025											
		A0705		Battery Problem			01/01/2025	31/01/2025											
		F1203	Life Threatening Illness or Injury	A0705			Battery Problem	01/01/2025	31/01/2025										
		A0709		Device Sensing Problem			01/01/2025	31/01/2025											
		A071302		Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025													
		A0705		Battery Problem	01/01/2025	31/01/2025													
		F1905	Device Revision or Replacement	A0705	Battery Problem	01/01/2025	31/01/2025												
		A0709		Device Sensing Problem	01/01/2025	31/01/2025													
		A071302		Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025													
		A0705		Battery Problem	01/01/2025	31/01/2025													
CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0705	Battery Problem	01/01/2025	31/01/2025												

								A0709	Device Sensing Problem	01/01/2025	31/01/2025
							F08	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
								A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
							F10	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
								A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
							F1203	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
								A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
							F1905	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
								A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
					CT2866	Implantable cardiac electrical stimulators	E210401	A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
							F08	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
								A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
							F10	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
								A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
							F1203	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
								A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
							F1905	A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
								A0705	Battery Problem	01/01/2025	31/01/2025
								A0709	Device Sensing Problem	01/01/2025	31/01/2025
								A071302	Inappropriate/Inadequate Shock/Stimulation	01/01/2025	31/01/2025
6671	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	A070909	Oversensing		
								A072201	High Impedance		
								A1301	Failure to Read Input Signal		
							F10	A070909	Oversensing		
								A072201	High Impedance		
								A1301	Failure to Read Input Signal		
6672	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	A072001	Electromagnetic Interference		
								A160503	Inappropriate or Unexpected Reset		
							F26	A072001	Electromagnetic Interference		
								A160503	Inappropriate or Unexpected Reset		
6673	2025	All other reportable incidents	47040	Triple-chamber implantable defibrillator	CT1150	Defibrillators	E2403	A070101	Failure to Capture		
							F10	A070101	Failure to Capture		
							E2403	A070101	Failure to Capture		
							F10	A070101	Failure to Capture		
							E2403	A070101	Failure to Capture		
							F10	A070101	Failure to Capture		
6674	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	A0712	Pacing Problem		
							F10	A0712	Pacing Problem		
							E2403	A0712	Pacing Problem		
							F10	A0712	Pacing Problem		
							E2403	A0712	Pacing Problem		
							F10	A0712	Pacing Problem		
6675	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F1001	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F1203	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F2307	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							E060109	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F1001	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F1203	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F2307	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							E060109	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F1001	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F1203	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
							F2307	A0709	Device Sensing Problem		
								A071301	Failure to Deliver Shock/Stimulation		
6676	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	A070504	Premature Discharge of Battery	13/06/2025	13/06/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/06/2025	13/06/2025
							F08	A070504	Premature Discharge of Battery	13/06/2025	13/06/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/06/2025	13/06/2025
							F1905	A070504	Premature Discharge of Battery	13/06/2025	13/06/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	13/06/2025	13/06/2025
6677	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	A071201	Failure to Convert Rhythm	28/01/2025	28/01/2025
								A072201	High Impedance	28/01/2025	28/01/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/01/2025	28/01/2025

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						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/04/2025	23/04/2025
								A0722	Impedance Problem	23/04/2025	23/04/2025
						F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2025	23/04/2025
								A070504	Premature Discharge of Battery	23/04/2025	23/04/2025
								A0722	Impedance Problem	23/04/2025	23/04/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2025	23/04/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2025
								A0722	Impedance Problem	23/04/2025	23/04/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2025	23/04/2025
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/04/2025	23/04/2025
								A0722	Impedance Problem	23/04/2025	23/04/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2025	23/04/2025
						F1903	Device Explanation	A070504	Premature Discharge of Battery	23/04/2025	23/04/2025
								A0722	Impedance Problem	23/04/2025	23/04/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2025	23/04/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2025
								A0722	Impedance Problem	23/04/2025	23/04/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2025	23/04/2025
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/04/2025	23/04/2025
								A0722	Impedance Problem	23/04/2025	23/04/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2025	23/04/2025
						F1903	Device Explanation	A070504	Premature Discharge of Battery	23/04/2025	23/04/2025
								A0722	Impedance Problem	23/04/2025	23/04/2025
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2025	23/04/2025
6682	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2025
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	27/03/2025
6683	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/03/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/03/2025
6684	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/05/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/05/2025
6685	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator		CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem
									A070504	Premature Discharge of Battery	
									A070602	Delayed Charge Time	
								F26	No Health Consequences or Impact	A0705	Battery Problem
									A070504	Premature Discharge of Battery	
									A070602	Delayed Charge Time	
									A0705	Battery Problem	
									A070504	Premature Discharge of Battery	
									A070602	Delayed Charge Time	
									A0705	Battery Problem	
									A070504	Premature Discharge of Battery	
									A070602	Delayed Charge Time	
									A0705	Battery Problem	
									A070504	Premature Discharge of Battery	

					CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A070910	Undersensing		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
						F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
						F1203		Life Threatening Illness or Injury	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
									A0712	Pacing Problem		
						F15		Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071202	Itacaccurate Synchronization		
6688	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
						F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F12		Serious Injury/ Illness/ Impairment	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F1905		Device Revision or Replacement	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F2307		Reprogramming of Device	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
						F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F12		Serious Injury/ Illness/ Impairment	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F1905		Device Revision or Replacement	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F2307		Reprogramming of Device	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
						F08		Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
						F12		Serious Injury/ Illness/ Impairment	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
						F1905		Device Revision or Replacement	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F2307		Reprogramming of Device	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F08		Hospitalization or Prolonged Hospitalization	A1605	Reset Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F12		Serious Injury/ Illness/ Impairment	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
						F1905		Device Revision or Replacement	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
						F2307		Reprogramming of Device	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
						F08		Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F12		Serious Injury/ Illness/ Impairment	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F1905		Device Revision or Replacement	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
						F2307		Reprogramming of Device	A1605	Reset Problem	28/01/2025	28/01/2025
									A0705	Battery Problem	28/01/2025	28/01/2025
									A070504	Premature Discharge of Battery	28/01/2025	28/01/2025
									A1605	Reset Problem	28/01/2025	28/01/2025
6689	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing	24/01/2025	24/01/2025
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/01/2025	24/01/2025

							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	24/01/2025	24/01/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	24/01/2025	24/01/2025
							F1903	Device Explanation	A070909	Oversensing	24/01/2025	24/01/2025
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	24/01/2025	24/01/2025
									A070909	Oversensing	24/01/2025	24/01/2025
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/01/2025	24/01/2025
8690	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8691	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
8692	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	01/12/2025	01/12/2025
									A070504	Premature Discharge of Battery	01/12/2025	01/12/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/12/2025	01/12/2025
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	01/12/2025	01/12/2025	
									A070504	Premature Discharge of Battery	01/12/2025	01/12/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/12/2025	01/12/2025
						F1905	Device Revision or Replacement	A0705	Battery Problem	01/12/2025	01/12/2025	
									A070504	Premature Discharge of Battery	01/12/2025	01/12/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	01/12/2025	01/12/2025
8693	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8694	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/05/2025	07/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025
8695	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E020204	Malaise	A070909	Oversensing	22/08/2024	22/08/2024
									A070910	Undersensing	22/08/2024	22/08/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
									A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
									A070909	Oversensing	22/08/2024	22/08/2024
									A070910	Undersensing	22/08/2024	22/08/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
									A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
									A070909	Oversensing	22/08/2024	22/08/2024
									A070910	Undersensing	22/08/2024	22/08/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
									A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
									A070909	Oversensing	22/08/2024	22/08/2024
									A070910	Undersensing	22/08/2024	22/08/2024

CT1150	Defibrillators	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
		F23	Unexpected Medical Intervention	A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
		E020204	Malaise	A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
		E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
	F1905	Device Revision or Replacement	A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
		F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
CT1258	Implantable defibrillators	E020204	Malaise	A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
		E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
F1905	Device Revision or Replacement	A070909	Oversensing	22/08/2024	22/08/2024		
		A070910	Undersensing	22/08/2024	22/08/2024		
		A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024		
		A090801	Signal Artifact/Noise	22/08/2024	22/08/2024		
		A070909	Oversensing	22/08/2024	22/08/2024		
		A070910	Undersensing	22/08/2024	22/08/2024		
	F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
CT1263	Cardiographs and associated devices	E020204	Malaise	A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
		E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
	F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
F1905	Device Revision or Replacement	A070909	Oversensing	22/08/2024	22/08/2024		
		A070910	Undersensing	22/08/2024	22/08/2024		
		A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024		
		A090801	Signal Artifact/Noise	22/08/2024	22/08/2024		
		A070909	Oversensing	22/08/2024	22/08/2024		
		A070910	Undersensing	22/08/2024	22/08/2024		
	F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
CT1286	Implantable cardiac electrical stimulators	E020204	Malaise	A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
				A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
				A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
				A070909	Oversensing	22/08/2024	22/08/2024
				A070910	Undersensing	22/08/2024	22/08/2024
	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	
			A070909	Oversensing	22/08/2024	22/08/2024	
			A070910	Undersensing	22/08/2024	22/08/2024	
			A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024	
			A090801	Signal Artifact/Noise	22/08/2024	22/08/2024	

									A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	22/08/2024	22/08/2024
									A070910	Undersensing	22/08/2024	22/08/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
									A070909	Oversensing	22/08/2024	22/08/2024
									A070910	Undersensing	22/08/2024	22/08/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
							F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
									A070909	Oversensing	22/08/2024	22/08/2024
									A070910	Undersensing	22/08/2024	22/08/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
									A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
							F23	Unexpected Medical Intervention	A070909	Oversensing	22/08/2024	22/08/2024
									A070910	Undersensing	22/08/2024	22/08/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	22/08/2024	22/08/2024
									A090801	Signal Artifact/Noise	22/08/2024	22/08/2024
6696	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
6697	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
6698	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	06/03/2025	06/03/2025
6699	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	19/11/2024	19/11/2024
									A090801	Signal Artifact/Noise	19/11/2024	19/11/2024
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	19/11/2024	19/11/2024
									A090801	Signal Artifact/Noise	19/11/2024	19/11/2024
							F1905	Device Revision or Replacement	A070909	Oversensing	19/11/2024	19/11/2024
									A090801	Signal Artifact/Noise	19/11/2024	19/11/2024
6700	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E0112	Dizziness	A070101	Failure to Capture		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							E060101	Asystole	A070101	Failure to Capture		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F22	Unexpected Diagnostic Intervention	A070101	Failure to Capture		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
6701	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
6702	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
									A070909	Oversensing		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A010402	Migration		
									A070909	Oversensing		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A010402	Migration		
									A070909	Oversensing		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
							F23	Unexpected Medical Intervention	A010402	Migration		
									A070909	Oversensing		
									A070910	Undersensing		
									A070910	Undersensing		
6703	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E020201	Anxiety	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		

								F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
8704	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						CT258	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						CT2866	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
8705	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
							F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
							F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
8706	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F05	Delay to Treatment/ Therapy	A070909	Oversensing			
8707	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/06/2025	05/06/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/06/2025	05/06/2025	
							F1903	Device Explantation	A070504	Premature Discharge of Battery	05/06/2025	05/06/2025	
8708	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/11/2024	07/11/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/11/2024	07/11/2024	
									A070504	Premature Discharge of Battery	07/11/2024	07/11/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/11/2024	07/11/2024	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	07/11/2024	07/11/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/11/2024	07/11/2024	
8709	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	11/02/2025	11/02/2025	
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	11/02/2025	11/02/2025	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	11/02/2025	11/02/2025	
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	11/02/2025	11/02/2025	
8710	2025		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F1905	Device Revision or Replacement	A0705	Battery Problem			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F1905	Device Revision or Replacement	A0705	Battery Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F1905	Device Revision or Replacement	A0705	Battery Problem			
8711	2025		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F1905	Device Revision or Replacement	A0705	Battery Problem			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F1905	Device Revision or Replacement	A0705	Battery Problem			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem			
							F1905	Device Revision or Replacement	A0705	Battery Problem			
8712	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/06/2025	12/06/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/06/2025	12/06/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/06/2025	12/06/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/06/2025	12/06/2025	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/06/2025	12/06/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/06/2025	12/06/2025	
8713	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
									A070909	Oversensing			
8714	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/03/2025	05/03/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/03/2025	05/03/2025	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/03/2025	05/03/2025	
8715	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/04/2025	15/04/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/04/2025	15/04/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/04/2025	15/04/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/04/2025	15/04/2025	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/04/2025	15/04/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	15/04/2025	15/04/2025	
8716	2025		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem			
									A1207	Incomplete or Inadequate Connection			
							F2301	Additional Device Required	A0711	Interrogation Problem			
									A1207	Incomplete or Inadequate Connection			
8717	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
8718	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/12/2024	23/12/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/12/2024	23/12/2024	
									A070504	Premature Discharge of Battery	23/12/2024	23/12/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/12/2024	23/12/2024	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/12/2024	23/12/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/12/2024	23/12/2024	
8719	2025		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0602	Cardiac Arrest	A07	Electrical /Electronic Property Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F02	Death	A07	Electrical /Electronic Property Problem			

					CT1150	Defibrillators	E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation		
							F02	Death	A07	Electrical /Electronic Property Problem		
									A071301	Failure to Deliver Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E0602	Cardiac Arrest	A07	Failure to Deliver Shock/Stimulation		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
					CT263	Cardiographs and associated devices	E0602	Cardiac Arrest	A071301	Failure to Deliver Shock/Stimulation		
							F02	Death	A07	Electrical /Electronic Property Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E0602	Cardiac Arrest	A07	Electrical /Electronic Property Problem		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A07	Electrical /Electronic Property Problem		
									A071301	Failure to Deliver Shock/Stimulation		
8720	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Overensing	04/11/2024	04/11/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	04/11/2024	04/11/2024
									A070909	Overensing	04/11/2024	04/11/2024
									A071302	Inappropriate/Inadequate Shock/Stimulation	04/11/2024	04/11/2024
8721	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A070909	Overensing		
									A0712	Pacing Problem		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
8722	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
									A150202	Malposition of Device		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
									A150202	Malposition of Device		
							F1904	Device Repositioning	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
									A150202	Malposition of Device		
							F2203	Imaging Required	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
									A150202	Malposition of Device		
8723	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A072201	High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
									A070909	Overensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
									A070909	Overensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
									A070909	Overensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
									A070909	Overensing		
									A072201	High Impedance		
8724	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/12/2024	20/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/12/2024	20/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/12/2024	20/12/2024
8725	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

								F2307	Reprogramming of Device	A0709	Device Sensing Problem			
										A0712	Pacing Problem			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators		E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem			
										A0712	Pacing Problem			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
										A0712	Pacing Problem			
								F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation			
										A0709	Device Sensing Problem			
										A0712	Pacing Problem			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
								F2307	Reprogramming of Device	A0709	Device Sensing Problem			
										A0712	Pacing Problem			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators		E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem			
										A0712	Pacing Problem			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
										A0712	Pacing Problem			
								F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation			
										A0709	Device Sensing Problem			
										A0712	Pacing Problem			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
								F2307	Reprogramming of Device	A0709	Device Sensing Problem			
										A0712	Pacing Problem			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
6726	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	15/03/2025		15/03/2025
6727	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	04/10/2024		04/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
										A0705	Battery Problem	04/10/2024		04/10/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
6728	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators		E210401	Shock from Patient Lead(s)	A070504	Premature Discharge of Battery	04/10/2024		04/10/2024
										A040101	Fracture	14/02/2025		14/02/2025
										A070909	Oversensing	14/02/2025		14/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	14/02/2025		14/02/2025
										A090801	Signal Artifact/Noise	14/02/2025		14/02/2025
								F08	Hospitalization or Prolonged Hospitalization	A040101	Fracture	14/02/2025		14/02/2025
										A070909	Oversensing	14/02/2025		14/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	14/02/2025		14/02/2025
										A090801	Signal Artifact/Noise	14/02/2025		14/02/2025
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A040101	Fracture	14/02/2025		14/02/2025
										A070909	Oversensing	14/02/2025		14/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	14/02/2025		14/02/2025
										A090801	Signal Artifact/Noise	14/02/2025		14/02/2025
										A070909	Oversensing	14/02/2025		14/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	14/02/2025		14/02/2025
										A090801	Signal Artifact/Noise	14/02/2025		14/02/2025
								F2203	Imaging Required	A040101	Fracture	14/02/2025		14/02/2025

										A070909	Oversensing	14/02/2025	14/02/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	14/02/2025	14/02/2025
										A090801	Signal Artifact/Noise	14/02/2025	14/02/2025
8729	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0722	Impedance Problem		
										A072201	High Impedance		
										A1206	Misconnection		
							F08	Hospitalization or Prolonged Hospitalization		A0722	Impedance Problem		
										A072201	High Impedance		
										A1206	Misconnection		
							F12	Serious Injury/ Illness/ Impairment		A0722	Impedance Problem		
										A072201	High Impedance		
										A1206	Misconnection		
							F1905	Device Revision or Replacement		A0722	Impedance Problem		
										A072201	High Impedance		
										A1206	Misconnection		
							F2307	Reprogramming of Device		A0722	Impedance Problem		
										A072201	High Impedance		
										A1206	Misconnection		
8730	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8731	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance	27/02/2025	27/02/2025
							F08	Hospitalization or Prolonged Hospitalization		A072201	High Impedance	27/02/2025	27/02/2025
							F1905	Device Revision or Replacement		A072201	High Impedance	27/02/2025	27/02/2025
8732	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
8733	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
						CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
						CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	21/05/2025	21/05/2025
8734	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0112	Dizziness		A070101	Failure to Capture		
							F26	No Health Consequences or Impact		A070101	Failure to Capture		
						CT258	Implantable defibrillators	E0112	Dizziness	A070101	Failure to Capture		
							F26	No Health Consequences or Impact		A070101	Failure to Capture		
						CT2866	Implantable cardiac electrical stimulators	E0112	Dizziness	A070101	Failure to Capture		
							F26	No Health Consequences or Impact		A070101	Failure to Capture		
8735	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
										A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact		A070909	Oversensing		
										A072001	Electromagnetic Interference		
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact		A070909	Oversensing		
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact		A070909	Oversensing		
										A072001	Electromagnetic Interference		
8736	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	14/03/2025	14/03/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	14/03/2025	14/03/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	14/03/2025	14/03/2025
8737	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0712	Pacing Problem		
8738	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8739	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	11/04/2025	11/04/2025
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/04/2025	11/04/2025
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery	11/04/2025	11/04/2025
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/04/2025	11/04/2025
8740	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060110	Ventricular Fibrillation		A0709	Device Sensing Problem		
										A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
										A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury		A0709	Device Sensing Problem		
										A0712	Pacing Problem		
							F2307	Reprogramming of Device		A0709	Device Sensing Problem		

					CT1150	Defibrillators	E060110	Ventricular Fibrillation	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
					CT263	Cardiographs and associated devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
6741	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	13/08/2025	13/08/2025
									A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	13/08/2025	13/08/2025
									A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	13/08/2025	13/08/2025
									A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
6742	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
6743	2025		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A071204	No Pacing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071204	No Pacing		
6744	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A0713	Defibrillation/Stimulation Problem		
									A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT1150	Defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A0713	Defibrillation/Stimulation Problem		
									A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A0713	Defibrillation/Stimulation Problem		
									A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT263	Cardiographs and associated devices	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A0713	Defibrillation/Stimulation Problem		
									A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
					CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0713	Defibrillation/Stimulation Problem		
6745	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	21/05/2024	21/05/2024
							F26	No Health Consequences or Impact	A0711	Interrogation Problem	21/05/2024	21/05/2024
6746	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/03/2025	31/03/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/03/2025	31/03/2025

					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	24/04/2025	24/04/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/04/2025	24/04/2025
							F1905	Device Revision or Replacement	A070504	Incorrect, Inadequate or Imprecise Result or Readings	24/04/2025	24/04/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/04/2025	24/04/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/04/2025	24/04/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/04/2025	24/04/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/04/2025	24/04/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	24/04/2025	24/04/2025
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/04/2025	24/04/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	24/04/2025	24/04/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/04/2025	24/04/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	24/04/2025	24/04/2025
6753	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A150202	Malposition of Device		
6754	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
							F1905	Device Revision or Replacement	A150202	Malposition of Device		
6755	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/05/2025	12/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/05/2025	12/05/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/05/2025	12/05/2025
6756	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	12/05/2025	12/05/2025
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
6757	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
6758	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
6759	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0203	Defective Device	12/12/2024	12/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/12/2024	12/12/2024
							F1905	Device Revision or Replacement	A0203	Defective Device	12/12/2024	12/12/2024
6760	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2024	12/12/2024
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
6761	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A150202	Malposition of Device		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
6762	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
6763	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		

6764	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem									
							F11	Non-Serious Injury/ Illness/ Impairment	A0712	Pacing Problem									
									A0709	Device Sensing Problem									
									A0712	Pacing Problem									
					CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem									
									A0712	Pacing Problem									
							F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem									
									A0712	Pacing Problem									
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem									
									A0712	Pacing Problem									
							F11	Non-Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem									
									A0712	Pacing Problem									
6765	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator									
							F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator									
							E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator									
							F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator									
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator									
							F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator									
							E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator									
							F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator									
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator									
							F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator									
							E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator									
							F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator									
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator														
		F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator														
		E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator														
		F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator														
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator														
		F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator														
		E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator														
		F26	No Health Consequences or Impact	A180601	Premature Elective Replacement Indicator														
6766	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2025	27/03/2025							
6767	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025							
							F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem	11/07/2025	11/07/2025							
							A070504	Premature Discharge of Battery	11/07/2025	11/07/2025									
							A0722	Impedance Problem	11/07/2025	11/07/2025									
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025							
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025							
							A0722	Impedance Problem	11/07/2025	11/07/2025									
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025							
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025							
							A0722	Impedance Problem	11/07/2025	11/07/2025									
CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025												
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025												
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025												
		A0722	Impedance Problem	11/07/2025	11/07/2025														
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025												
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025												
		F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025												
		A0722	Impedance Problem	11/07/2025	11/07/2025														
6768	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing									
									A0712	Pacing Problem									
									A090801	Signal Artifact/Noise									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal									
									A070909	Oversensing									
									A0712	Pacing Problem									
									A090801	Signal Artifact/Noise									
									A1301	Failure to Read Input Signal									
							6769	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A070910	Undersensing		
																A0909	Unexpected Therapeutic Results		
																A1301	Failure to Read Input Signal		
														F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
		A0909	Unexpected Therapeutic Results																
		A1301	Failure to Read Input Signal																
F1203	Life Threatening Illness or Injury	A070910	Undersensing																
		A0909	Unexpected Therapeutic Results																
		A1301	Failure to Read Input Signal																
6770	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators								E060110	Ventricular Fibrillation	A070910	Undersensing		
																A0909	Unexpected Therapeutic Results		
																A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing									
									A0909	Unexpected Therapeutic Results									
									A1301	Failure to Read Input Signal									
							F1203	Life Threatening Illness or Injury	A070910	Undersensing									
									A0909	Unexpected Therapeutic Results									
									A1301	Failure to Read Input Signal									
									A0909	Unexpected Therapeutic Results									

									A1301	Failure to Read Input Signal		
6771	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
6772	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
6773	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
6774	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	20/06/2025	20/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/06/2025	20/06/2025
6775	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

						CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A072201	High Impedance		
								E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
6776	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	21/03/2025	21/03/2025
								F26	No Health Consequences or Impact	A1206	Misconnection	21/03/2025	21/03/2025
										A05	Mechanical Problem	21/03/2025	21/03/2025
6777	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1206	Misconnection	21/03/2025	21/03/2025
										A070909	Oversensing		
								F23	Unexpected Medical Intervention	A071204	No Pacing		
										A070909	Oversensing		
6778	2025		37265	Dual-chamber implantable defibrillator	CT1150		Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071204	No Pacing		
										A0709	Device Sensing Problem		
								F05	Delay to Treatment/ Therapy	A110301	Delayed Program or Algorithm Execution		
										A0709	Device Sensing Problem		
					CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A110301	Delayed Program or Algorithm Execution		
								F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
										A110301	Delayed Program or Algorithm Execution		
					CT2866		Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F05	Delay to Treatment/ Therapy	A110301	Delayed Program or Algorithm Execution		
										A0709	Device Sensing Problem		
6779	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150		Defibrillators	E210401	Shock from Patient Lead(s)	A110301	Delayed Program or Algorithm Execution		
										A0709	Device Sensing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
								F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258		Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
								F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
					CT2866		Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
6780	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258		Implantable defibrillators	E060101	Asystole	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070101	Failure to Capture		
										A070910	Undersensing		
										A071201	Failure to Convert Rhythm		
										A0909	Unexpected Therapeutic Results		
								F1203	Life Threatening Illness or Injury	A070101	Failure to Capture		
										A070910	Undersensing		
										A071201	Failure to Convert Rhythm		
										A0909	Unexpected Therapeutic Results		
								F1908	Prolonged Surgery	A070101	Failure to Capture		
										A070910	Undersensing		
										A071201	Failure to Convert Rhythm		
										A0909	Unexpected Therapeutic Results		
								F2306	Resuscitation	A070101	Failure to Capture		
										A070910	Undersensing		
										A071201	Failure to Convert Rhythm		
										A0909	Unexpected Therapeutic Results		
6781	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150		Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A072001	Electromagnetic Interference		
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A072001	Electromagnetic Interference		
					CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A072001	Electromagnetic Interference		
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A072001	Electromagnetic Interference		
					CT2866		Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A072001	Electromagnetic Interference		
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
6782	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A072201	High Impedance		
								F1001	Absence of Treatment	A070909	Oversensing		
										A072201	High Impedance		
6783	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258		Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
										A1301	Failure to Read Input Signal		
								F26	No Health Consequences or Impact	A072201	High Impedance		
										A1301	Failure to Read Input Signal		

6784	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings				
					F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings						
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings				
					F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings						
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings				
					F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings						
6785	2025	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	07/05/2025	07/05/2025		
							A070504	Premature Discharge of Battery	07/05/2025	07/05/2025				
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025				
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	07/05/2025	07/05/2025		
							A070504	Premature Discharge of Battery	07/05/2025	07/05/2025				
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025				
							F1905	Device Revision or Replacement	A0705	Battery Problem	07/05/2025	07/05/2025		
							A070504	Premature Discharge of Battery	07/05/2025	07/05/2025				
			A0908	Incorrect, Inadequate or Imprecise Result or Readings	07/05/2025	07/05/2025								
6786	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing	26/03/2025	26/03/2025		
							A071302	Inappropriate/Inadequate Shock/Stimulation	26/03/2025	26/03/2025				
							A090801	Signal Artifact/Noise	26/03/2025	26/03/2025				
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	26/03/2025	26/03/2025		
							A071302	Inappropriate/Inadequate Shock/Stimulation	26/03/2025	26/03/2025				
							A090801	Signal Artifact/Noise	26/03/2025	26/03/2025				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	26/03/2025	26/03/2025		
							A071302	Inappropriate/Inadequate Shock/Stimulation	26/03/2025	26/03/2025				
							A090801	Signal Artifact/Noise	26/03/2025	26/03/2025				
							F1905	Device Revision or Replacement	A070909	Oversensing	26/03/2025	26/03/2025		
			A071302	Inappropriate/Inadequate Shock/Stimulation	26/03/2025	26/03/2025								
			A090801	Signal Artifact/Noise	26/03/2025	26/03/2025								
6787	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/04/2025	01/04/2025		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/04/2025	01/04/2025		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/04/2025	01/04/2025		
6788	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing				
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A072201	High Impedance		
									A090801	Signal Artifact/Noise	A070909	Oversensing		
									F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A072201	High Impedance		
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									A090801	Signal Artifact/Noise	A070909	Oversensing		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing				
									A071302	Inappropriate/Inadequate Shock/Stimulation	A072201	High Impedance		
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A072201	High Impedance		
									F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
									A070909	Oversensing	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A072201	High Impedance		
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									A090801	Signal Artifact/Noise	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing				
									A071302	Inappropriate/Inadequate Shock/Stimulation	A072201	High Impedance		
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A072201	High Impedance		
									F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
									A070909	Oversensing	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation	A072201	High Impedance		
									A072201	High Impedance	A090801	Signal Artifact/Noise		
									A090801	Signal Artifact/Noise	A070909	Oversensing		
6789	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem				
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem				
									A071302	Inappropriate/Inadequate Shock/Stimulation				
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem				
									A071302	Inappropriate/Inadequate Shock/Stimulation				
									F10	Inadequate/Inappropriate Treatment or Diagnostic	A0709	Device Sensing Problem		

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							F08	Hospitalization or Prolonged Hospitalization	A071302 A070909 A071302	Inappropriate/Inadequate Shock/Stimulation Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
6801	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070603	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
							F1901	Additional Surgery	A0508 A070603	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070603	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
							F1901	Additional Surgery	A0508 A070903	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
					CT1258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070603	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
							F1901	Additional Surgery	A0508 A070603	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070603	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
							F1901	Additional Surgery	A0508 A070603	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070603	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
							F1901	Additional Surgery	A0508 A070903	Noise, Audible Failure to Charge	17/04/2025 17/04/2025	17/04/2025 17/04/2025
6802	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301 F08	Failure to Charge Hospitalization or Prolonged Hospitalization	17/04/2025 01/04/2025	17/04/2025 01/04/2025
							F1001	Absence of Treatment	A1301	Failure to Read Input Signal	01/04/2025	01/04/2025
							F1906	Modified Surgical Procedure	A1301	Failure to Read Input Signal	01/04/2025	01/04/2025
							F1908	Prolonged Surgery	A1301	Failure to Read Input Signal	01/04/2025	01/04/2025
6803	2025		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0102	Brain Injury	A071301	Failure to Deliver Shock/Stimulation		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
							E0102	Brain Injury	A071301	Failure to Deliver Shock/Stimulation		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
					CT2866	implantable cardiac electrical stimulators	F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
							E0102	Brain Injury	A071301	Failure to Deliver Shock/Stimulation		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071301	Failure to Deliver Shock/Stimulation		
6804	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A0712 A071302	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A0712 A071302	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A0712 A071302	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709 A0712 A071302	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
6805	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
							F1203	Life Threatening Illness or Injury	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
							F1903	Device Explanation	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
							F2203	Imaging Required	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
							F2307	Reprogramming of Device	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A072001 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise	25/05/2025 25/05/2025 25/05/2025 25/05/2025	25/05/2025 25/05/2025 25/05/2025 25/05/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation	25/05/2025 25/05/2025	25/05/2025 25/05/2025

						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F1203	Life Threatening Illness or Injury	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
				F1903	Device Explanation	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
						A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
				F2203	Imaging Required	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
						A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
				F2307	Reprogramming of Device	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
						A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				CT258	Implantable defibrillators	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
				F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
						A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F1203	Life Threatening Illness or Injury	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F1903	Device Explanation	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F2203	Imaging Required	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F2307	Reprogramming of Device	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				CT263	Cardiographs and associated devices	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
				F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
						A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F1203	Life Threatening Illness or Injury	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F1903	Device Explanation	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F2203	Imaging Required	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F2307	Reprogramming of Device	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				CT2866	Implantable cardiac electrical stimulators	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
				F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
						A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025
						A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
				F1203	Life Threatening Illness or Injury	A070909	Oversensing	25/05/2025	25/05/2025
						A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
						A072001	Electromagnetic Interference	25/05/2025	25/05/2025

								F1903	Device Explanation	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
										A070909	Oversensing	25/05/2025	25/05/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
										A072001	Electromagnetic Interference	25/05/2025	25/05/2025
								F2203	Imaging Required	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
										A070909	Oversensing	25/05/2025	25/05/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
										A072001	Electromagnetic Interference	25/05/2025	25/05/2025
								F2307	Reprogramming of Device	A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
										A070909	Oversensing	25/05/2025	25/05/2025
										A071302	Inappropriate/Inadequate Shock/Stimulation	25/05/2025	25/05/2025
										A072001	Electromagnetic Interference	25/05/2025	25/05/2025
										A090801	Signal Artifact/Noise	25/05/2025	25/05/2025
8806	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8807	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070910	Undersensing		
										A0713	Defibrillation/Stimulation Problem		
							F05	Delay to Treatment/ Therapy		A070910	Undersensing		
										A0713	Defibrillation/Stimulation Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070910	Undersensing		
										A0713	Defibrillation/Stimulation Problem		
							F05	Delay to Treatment/ Therapy		A070910	Undersensing		
										A0713	Defibrillation/Stimulation Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A070910	Undersensing		
										A0713	Defibrillation/Stimulation Problem		
							F05	Delay to Treatment/ Therapy		A070910	Undersensing		
										A0713	Defibrillation/Stimulation Problem		
8808	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0713	Defibrillation/Stimulation Problem		
										A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
8809	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	24/03/2025	24/03/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	24/03/2025	24/03/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	24/03/2025	24/03/2025
8810	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A1301	Failure to Read Input Signal	01/04/2025	01/04/2025
							F08	Hospitalization or Prolonged Hospitalization		A1301	Failure to Read Input Signal	01/04/2025	01/04/2025
							F1001	Absence of Treatment		A1301	Failure to Read Input Signal	01/04/2025	01/04/2025
							F1906	Modified Surgical Procedure		A1301	Failure to Read Input Signal	01/04/2025	01/04/2025
							F1908	Prolonged Surgery		A1301	Failure to Read Input Signal	01/04/2025	01/04/2025
8811	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F08	Hospitalization or Prolonged Hospitalization		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F1905	Device Revision or Replacement		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F23	Unexpected Medical Intervention		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
8812	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F08	Hospitalization or Prolonged Hospitalization		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F1905	Device Revision or Replacement		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
							F23	Unexpected Medical Intervention		A071302	Inappropriate/Inadequate Shock/Stimulation	23/06/2025	23/06/2025
8813	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact		A070504	Premature Discharge of Battery		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8814	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)		A010402	Migration		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A1301	Failure to Read Input Signal		
										A010402	Migration		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
							F2203	Imaging Required		A1301	Failure to Read Input Signal		
										A010402	Migration		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)		A010402	Migration		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A1301	Failure to Read Input Signal		
										A010402	Migration		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
							F2203	Imaging Required		A1301	Failure to Read Input Signal		
										A010402	Migration		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
										A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)		A010402	Migration		
										A070909	Oversensing		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
						F2203	Imaging Required		A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)		A010402	Migration	
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A1301	Failure to Read Input Signal		
									A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
						F2203	Imaging Required		A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
					CT266	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)		A010402	Migration	
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
						F2203	Imaging Required		A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
8815	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
							F15	Recognized Device or Procedural Complication	A070101	Failure to Capture		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
							F15	Recognized Device or Procedural Complication	A070101	Failure to Capture		
					CT266	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
							F15	Recognized Device or Procedural Complication	A070101	Failure to Capture		
8816	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)		A010402	Migration	
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
						F2203	Imaging Required		A010402	Migration		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
8817	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F05	Delay to Treatment/ Therapy	A070909	Oversensing		
8818	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
8819	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A070909	Oversensing		
									A071202	Inaccurate Synchronization		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071202	Inaccurate Synchronization		
						F1203	Life Threatening Illness or Injury	A070909	Oversensing			
									A071202	Inaccurate Synchronization		
8820	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						E233001	Chest Pain		A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
8821	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909 A071302 A090801 A070909	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
							E233001	Chest Pain	A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
8822	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	23/06/2025	23/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	23/06/2025	23/06/2025
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	23/06/2025	23/06/2025
8823	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025
8824	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
8825	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	25/01/2025	25/01/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	25/01/2025	25/01/2025
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	25/01/2025	25/01/2025
8826	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A070912 A071301	Incorrect Interpretation of Signal Failure to Deliver Shock/Stimulation		
							F12	Serious Injury/Illness/ Impairment	A070912 A071301	Incorrect Interpretation of Signal Failure to Deliver Shock/Stimulation		
8827	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	Tachycardia	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	E060109	Tachycardia	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
8828	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8829	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
8830	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8831	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem		
							F2307	Reprogramming of Device	A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem		
							F2307	Reprogramming of Device	A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem		
							F2307	Reprogramming of Device	A0705	Battery Problem		
8832	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
8833	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
8834	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		

										A072001	Electromagnetic Interference		
								F2307	Reprogramming of Device	A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A072001	Electromagnetic Interference		
										A090801	Signal Artifact/Noise		
8835	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0709	Device Sensing Problem		
										A070909	Oversensing		
										A070910	Undersensing		
										A090801	Signal Artifact/Noise		
										A12	Connection Problem		
										A150202	Malposition of Device		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
										A070909	Oversensing		
										A070910	Undersensing		
										A090801	Signal Artifact/Noise		
										A12	Connection Problem		
										A150202	Malposition of Device		
							F2203	Imaging Required		A0709	Device Sensing Problem		
										A070909	Oversensing		
										A070910	Undersensing		
										A090801	Signal Artifact/Noise		
										A12	Connection Problem		
										A150202	Malposition of Device		
8836	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)		A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
8837	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070504	Premature Discharge of Battery	16/05/2025	16/05/2025
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	16/05/2025	16/05/2025
							F08	Hospitalization or Prolonged Hospitalization		A070504	Premature Discharge of Battery	16/05/2025	16/05/2025
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	16/05/2025	16/05/2025
							F1905	Device Revision or Replacement		A070504	Premature Discharge of Battery	16/05/2025	16/05/2025
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	16/05/2025	16/05/2025
8838	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT141	Electrodes/Leads and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT145	Cardiovascular devices	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT233	Surgical	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT2406	Implantable	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT2407	Active implantable	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT2727	Active implant devices/ancillaries	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT2985	Active	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT3001	Implantable metal	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT3002	Implantable synthetic polymer	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT3006	Implantable inorganic material	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT3007	Implantable ceramic	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT314	Electrically powered	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT321	Long-term surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT449	Generators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT981	Single use	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
					CT983	Surgical invasive	E2403	No Clinical Signs, Symptoms or Conditions		A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement		A160601	Premature Elective Replacement Indicator		
8839	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
8840	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock		A071201	Failure to Convert Rhythm		
							F08	Hospitalization or Prolonged Hospitalization		A071201	Failure to Convert Rhythm		
							F1905	Device Revision or Replacement		A071201	Failure to Convert Rhythm		
							F1908	Prolonged Surgery		A071201	Failure to Convert Rhythm		
							F22	Unexpected Diagnostic Intervention		A071201	Failure to Convert Rhythm		
							F2203	Imaging Required		A071201	Failure to Convert Rhythm		
							F2306	Resuscitation		A071201	Failure to Convert Rhythm		
8841	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2104	Electric Shock		A0101	Patient-Device Incompatibility		
										A071201	Failure to Convert Rhythm		

							F08	Hospitalization or Prolonged Hospitalization	A0101	Patient-Device Incompatibility			
							F1905	Device Revision or Replacement	A071201	Failure to Convert Rhythm			
									A0101	Patient-Device Incompatibility			
							F1908	Prolonged Surgery	A071201	Failure to Convert Rhythm			
							F22	Unexpected Diagnostic Intervention	A0101	Patient-Device Incompatibility			
									A071201	Failure to Convert Rhythm			
							F2203	Imaging Required	A0101	Patient-Device Incompatibility			
									A071201	Failure to Convert Rhythm			
							F2306	Resuscitation	A0101	Patient-Device Incompatibility			
									A071201	Failure to Convert Rhythm			
6842	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
									A090801	Signal Artifact/Noise			
							F23	Unexpected Medical Intervention	A070909	Overensing			
									A090801	Signal Artifact/Noise			
6843	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing			
									A090801	Signal Artifact/Noise			
							F23	Unexpected Medical Intervention	A070909	Overensing			
									A090801	Signal Artifact/Noise			
6844	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060103	Atrial Flutter	A0709	Device Sensing Problem			
									A070909	Overensing			
									A090801	Signal Artifact/Noise			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A070909	Overensing			
									A090801	Signal Artifact/Noise			
6845	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A0712	Pacing Problem			
							E060109	Tachycardia	A0712	Pacing Problem			
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem			
							F2307	Reprogramming of Device	A0712	Pacing Problem			
6846	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/05/2025	28/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/05/2025	28/05/2025	
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	28/05/2025	28/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/05/2025	28/05/2025	
6847	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
						CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
						CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F1001	Absence of Treatment	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
							F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A0712	Pacing Problem			
									A071301	Failure to Deliver Shock/Stimulation			
6848	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/05/2025	27/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/05/2025	27/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/05/2025	27/05/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025	
6849	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
									A070909	Overensing			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem			
									A070909	Overensing			
									A090801	Signal Artifact/Noise			
6850	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/06/2025	18/06/2025	
									A070504	Premature Discharge of Battery	18/06/2025	18/06/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/06/2025	18/06/2025	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	18/06/2025	18/06/2025	
									A070504	Premature Discharge of Battery	18/06/2025	18/06/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/06/2025	18/06/2025	
							F1905	Device Revision or Replacement	A0705	Battery Problem	18/06/2025	18/06/2025	

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								P2203	Imaging Required	A09801 A1301 A070504 A070909 A071302 A09801 A1301	Signal Artifact/Noise Failure to Read Input Signal Premature Discharge of Battery Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
6856	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
					CT263	Cardiographs end associated devices	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
6857	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	21/05/2025	21/05/2025	
							E210401	Shock from Patient Lead(s)	A0712 A071201 A071302	Pacing Problem Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071201 A071302	Pacing Problem Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0712 A071201 A071302	Pacing Problem Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071201 A071302	Pacing Problem Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0712 A071201 A071302	Pacing Problem Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071201 A071302	Pacing Problem Failure to Convert Rhythm Inappropriate/Inadequate Shock/Stimulation			
6858	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem			
							F2307	Reprogramming of Device	A0709	Device Sensing Problem			
6859	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
							F26	No Health Consequences or Impact	A072201	High Impedance			
6860	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT258	Implantable defibrillators	E2104	Electric Shock	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
6861	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A180103	Device Contamination with Body Fluid	06/05/2025	06/05/2025	
							F26	No Health Consequences or Impact	A180103	Device Contamination with Body Fluid	06/05/2025	06/05/2025	
6862	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT263	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
8863	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	E210401	Shock from Patient Lead(s)	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
								A150202	Malposition of Device			
						F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
								A150202	Malposition of Device			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
								A150202	Malposition of Device			
						F1905	Device Revision or Replacement	A070909	Oversensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
								A090801	Signal Artifact/Noise			
								A150202	Malposition of Device			
8864	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
						F26	No Health Consequences or Impact	A072201	High Impedance			
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
								A072201	High Impedance			
						F26	No Health Consequences or Impact	A010402	Migration			
								A072201	High Impedance			
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
								A072201	High Impedance			
						F26	No Health Consequences or Impact	A010402	Migration			
								A072201	High Impedance			
					CT263	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
								A072201	High Impedance			
						F26	No Health Consequences or Impact	A010402	Migration			
								A072201	High Impedance			
					CT2866	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration			
								A072201	High Impedance			
						F26	No Health Consequences or Impact	A010402	Migration			
								A072201	High Impedance			
8865	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F23	Unexpected Medical Intervention	A070504	Premature Discharge of Battery			
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								A070504	Premature Discharge of Battery			
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								A070504	Premature Discharge of Battery			
					CT263	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								A070504	Premature Discharge of Battery			
					CT2866	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								A070504	Premature Discharge of Battery			
						F23	Unexpected Medical Intervention	A070504	Premature Discharge of Battery			
8866	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT1150	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								A070504	Premature Discharge of Battery			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
					CT258	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								A070504	Premature Discharge of Battery			
					CT263	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								A070504	Premature Discharge of Battery			
					CT2866	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
								A070504	Premature Discharge of Battery			
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
8867	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			

					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302 A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F2307	Reprogramming of Device	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
6668	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 A070909 A070910 A090801 A12 A150202	Device Sensing Problem Oversensing Undersensing Signal Artifact/Noise Connection Problem Malposition of Device			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A070910 A090801 A12 A150202	Device Sensing Problem Oversensing Undersensing Signal Artifact/Noise Connection Problem Malposition of Device			
							F2203	Imaging Required	A0709 A070909 A070910 A090801 A12 A150202	Device Sensing Problem Oversensing Undersensing Signal Artifact/Noise Connection Problem Malposition of Device			
6669	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908 A070504 A0908 A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	10/06/2025 10/06/2025 10/06/2025 10/06/2025 10/06/2025 10/06/2025	10/06/2025 10/06/2025 10/06/2025 10/06/2025 10/06/2025 10/06/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	10/06/2025 10/06/2025	10/06/2025 10/06/2025	
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	10/06/2025 10/06/2025	10/06/2025 10/06/2025	
6670	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation			
6671	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing			
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing			
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070909	Oversensing Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing			
6672	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F2307	Reprogramming of Device	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
						CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
							F2307	Reprogramming of Device	A071302 A0709 A071302 A0709 A071302 A0709 A071302	Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
						CT1258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F2307	Reprogramming of Device	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
						CT1263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F2307	Reprogramming of Device	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
						CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F1203	Life Threatening Illness or Injury	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
							F2307	Reprogramming of Device	A0709 A071302 A0709 A071302 A0709 A071302 A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation			
6673	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation			

							E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
8874	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F12	Serious Injury/Illness/ Impairment	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F12	Serious Injury/Illness/ Impairment	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F12	Serious Injury/Illness/ Impairment	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F12	Serious Injury/Illness/ Impairment	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F12	Serious Injury/Illness/ Impairment	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
							F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	13/05/2025	13/05/2025
8875	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
8876	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
									A070910	Undersensing		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F15	Recognized Device or Procedural Complication	A070602	Delayed Charge Time		
									A070910	Undersensing		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
									A070910	Undersensing		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F15	Recognized Device or Procedural Complication	A070602	Delayed Charge Time		
									A070910	Undersensing		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
									A070910	Undersensing		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F15	Recognized Device or Procedural Complication	A070602	Delayed Charge Time		
									A070910	Undersensing		
									A072201	High Impedance		
									A1301	Failure to Read Input Signal		
8877	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
8878	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A090801	Signal Artifact/Noise		

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
8879	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
8880	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
8881	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8882	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
8883	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
									A13	Communication or Transmission Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A13	Communication or Transmission Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A13	Communication or Transmission Problem		
8884	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	12/12/2024	12/12/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	12/12/2024	12/12/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	12/12/2024	12/12/2024
8885	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
8886	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
6887	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
6888	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A072001	Electromagnetic Interference		
									A070909	Oversensing		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A072001	Electromagnetic Interference		
									A070909	Oversensing		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A072001	Electromagnetic Interference		
									A070909	Oversensing		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F12	Serious Injury/ Illness/ Impairment	A072001	Electromagnetic Interference		
									A070909	Oversensing		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
6889	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
6890	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
6891	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
									A1301	Failure to Read Input Signal		
						F15	Recognized Device or Procedural Complication		A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
									A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
							F15	Recognized Device or Procedural Complication	A1301	Failure to Read Input Signal		
									A070102	High Capture Threshold		
									A070504	Premature Discharge of Battery		
									A070910	Undersensing		
8892	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
							F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
									A160503	Inappropriate or Unexpected Reset		
8893	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070101	Failure to Capture		
									A070909	Oversensing		
							F23	Unexpected Medical Intervention	A090801	Signal Artifact/Noise		
									A070101	Failure to Capture		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
8894	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
8895	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E011903	Syncope/Fainting	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F1203	Life Threatening Illness or Injury	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
8896	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8897	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
									A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
									A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
									A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
									A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
									A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
									A071201	Failure to Convert Rhythm	27/05/2025	27/05/2025
									A072201	High Impedance	27/05/2025	27/05/2025
									A072202	Low Impedance	27/05/2025	27/05/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/05/2025	27/05/2025
8898	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8899	2025		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

						CT2866	Implantable cardiac electrical stimulators	F26 No Health Consequences or Impact E2403 No Clinical Signs, Symptoms or Conditions	A070504 Premature Discharge of Battery A070504 Premature Discharge of Battery										
6900	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605 Reset Problem A160503 Inappropriate or Unexpected Reset										
							F26	No Health Consequences or Impact	A1605 Reset Problem A160503 Inappropriate or Unexpected Reset										
							E2403	No Clinical Signs, Symptoms or Conditions	A1605 Reset Problem A160503 Inappropriate or Unexpected Reset										
							F26	No Health Consequences or Impact	A1605 Reset Problem A160503 Inappropriate or Unexpected Reset										
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605 Reset Problem A160503 Inappropriate or Unexpected Reset										
							F26	No Health Consequences or Impact	A1605 Reset Problem A160503 Inappropriate or Unexpected Reset										
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1605 Reset Problem A160503 Inappropriate or Unexpected Reset															
		F26	No Health Consequences or Impact	A1605 Reset Problem A160503 Inappropriate or Unexpected Reset															
6901	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909 Oversensing A071302 Inappropriate/Inadequate Shock/Stimulation A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
							F08	Hospitalization or Prolonged Hospitalization	A070909 Oversensing A071302 Inappropriate/Inadequate Shock/Stimulation A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 Oversensing A071302 Inappropriate/Inadequate Shock/Stimulation A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
							F1905	Device Revision or Replacement	A070909 Oversensing A071302 Inappropriate/Inadequate Shock/Stimulation A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
							F23	Unexpected Medical Intervention	A070909 Oversensing A071302 Inappropriate/Inadequate Shock/Stimulation A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
							E2403	No Clinical Signs, Symptoms or Conditions	A072201 High Impedance A072201 High Impedance										
							F26	No Health Consequences or Impact	A072201 High Impedance A072201 High Impedance										
							E2403	No Clinical Signs, Symptoms or Conditions	A072201 High Impedance A072201 High Impedance										
							F26	No Health Consequences or Impact	A072201 High Impedance A072201 High Impedance										
							E2403	No Clinical Signs, Symptoms or Conditions	A072201 High Impedance A072201 High Impedance										
							F26	No Health Consequences or Impact	A072201 High Impedance A072201 High Impedance										
							E2403	No Clinical Signs, Symptoms or Conditions	A072201 High Impedance A072201 High Impedance										
							F26	No Health Consequences or Impact	A072201 High Impedance A072201 High Impedance										
							E2403	No Clinical Signs, Symptoms or Conditions	A072201 High Impedance A072201 High Impedance										
							F26	No Health Consequences or Impact	A072201 High Impedance A072201 High Impedance										
							E2403	No Clinical Signs, Symptoms or Conditions	A070504 Premature Discharge of Battery A0908 Incorrect, Inadequate or Imprecise Result or Readings	09/09/2025	09/09/2025								
							F08	Hospitalization or Prolonged Hospitalization	A070504 Premature Discharge of Battery A0908 Incorrect, Inadequate or Imprecise Result or Readings	09/09/2025	09/09/2025								
							F1905	Device Revision or Replacement	A070504 Premature Discharge of Battery A0908 Incorrect, Inadequate or Imprecise Result or Readings	09/09/2025	09/09/2025								
							6904	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation			
														F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation			
F1203	Life Threatening Illness or Injury	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation																	
F2307	Reprogramming of Device	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation																	
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation															
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation															
		F1203	Life Threatening Illness or Injury	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation															
		F2307	Reprogramming of Device	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation															
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation															
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation															
		F1203	Life Threatening Illness or Injury	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation															
		F2307	Reprogramming of Device	A0709 Device Sensing Problem A071302 Inappropriate/Inadequate Shock/Stimulation															
6905	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 Premature Discharge of Battery A0908 Incorrect, Inadequate or Imprecise Result or Readings										
							F26	No Health Consequences or Impact	A070504 Premature Discharge of Battery A0908 Incorrect, Inadequate or Imprecise Result or Readings										
6906	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
							F26	No Health Consequences or Impact	A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
							F26	No Health Consequences or Impact	A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings										
CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201 High Impedance A0908 Incorrect, Inadequate or Imprecise Result or Readings															

							F26	No Health Consequences or Impact	A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8907	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8908	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2025	30/05/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2025	30/05/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	30/05/2025	30/05/2025
8909	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
							F1903	Device Explanation	A070504	Premature Discharge of Battery	13/08/2025	13/08/2025
8910	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
8911	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8912	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A070909	Oversensing		
									A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070102	High Capture Threshold		
									A070909	Oversensing		
									A070910	Undersensing		
8913	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
8914	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
							F26	No Health Consequences or Impact	A1107	Data Problem		
8915	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
8916	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0909	Unexpected Therapeutic Results		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0909	Unexpected Therapeutic Results		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0909	Unexpected Therapeutic Results		
							F2303	Medication Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0909	Unexpected Therapeutic Results		
8917	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0909	Unexpected Therapeutic Results		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0909	Unexpected Therapeutic Results		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0909	Unexpected Therapeutic Results		
							F2303	Medication Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

									A0909	Unexpected Therapeutic Results		
8918	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A051201	Device Dislodged or Dislocated		
							F26	No Health Consequences or Impact	A051201	Device Dislodged or Dislocated		
8919	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
8920	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A10402	Migration		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
									A10402	Migration		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
8921	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A1107	Data Problem		
									A070909	Oversensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8922	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
8923	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/06/2025	04/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/06/2025	04/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/06/2025	04/06/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	04/06/2025	04/06/2025
							F2203	Imaging Required	A070909	Oversensing	04/06/2025	04/06/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/06/2025	04/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/06/2025	04/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/06/2025	04/06/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	04/06/2025	04/06/2025
							F2203	Imaging Required	A070909	Oversensing	04/06/2025	04/06/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/06/2025	04/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/06/2025	04/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/06/2025	04/06/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	04/06/2025	04/06/2025
							F2203	Imaging Required	A070909	Oversensing	04/06/2025	04/06/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/06/2025	04/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/06/2025	04/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/06/2025	04/06/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	04/06/2025	04/06/2025
							F2203	Imaging Required	A070909	Oversensing	04/06/2025	04/06/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/06/2025	04/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	04/06/2025	04/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	04/06/2025	04/06/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	04/06/2025	04/06/2025
							F2203	Imaging Required	A070909	Oversensing	04/06/2025	04/06/2025
8924	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8925	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A0712	Pacing Problem		
8926	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8927	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F2307	Reprogramming of Device	A072202	Low Impedance		

					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance									
							F2307	Reprogramming of Device	A072202	Low Impedance									
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance									
							F2307	Reprogramming of Device	A072202	Low Impedance									
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance									
							F2307	Reprogramming of Device	A072202	Low Impedance									
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance									
							F2307	Reprogramming of Device	A072202	Low Impedance									
					6028	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference				
														A090801	Signal Artifact/Noise				
												F26	No Health Consequences or Impact	A072001	Electromagnetic Interference				
														A090801	Signal Artifact/Noise				
CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001								Electromagnetic Interference							
		F26	No Health Consequences or Impact	A072001								Electromagnetic Interference							
		A090801	Signal Artifact/Noise																
CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001								Electromagnetic Interference							
		F26	No Health Consequences or Impact	A090801								Signal Artifact/Noise							
		A072001	Electromagnetic Interference																
		A090801	Signal Artifact/Noise																
6029	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator								CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							A072001	Electromagnetic Interference											
					F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing											
							A072001	Electromagnetic Interference											
					F2307	Reprogramming of Device	A070909	Oversensing											
							A072001	Electromagnetic Interference											
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing									
							A072001	Electromagnetic Interference											
							A070909	Oversensing											
							A072001	Electromagnetic Interference											
							F2307	Reprogramming of Device	A070909	Oversensing									
							A072001	Electromagnetic Interference											
6030	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A073603	Oversensing									
									A071204	No Pacing									
							F23	Unexpected Medical Intervention	A070909	Oversensing									
									A071204	No Pacing									
							6031	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
																A0712	Pacing Problem		
																A071302	Inappropriate/Inadequate Shock/Stimulation		
														F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
																A0712	Pacing Problem		
																A071302	Inappropriate/Inadequate Shock/Stimulation		
																A0709	Device Sensing Problem		
																A0712	Pacing Problem		
		A071302	Inappropriate/Inadequate Shock/Stimulation																
		A0709	Device Sensing Problem																
		A0712	Pacing Problem																
		A071302	Inappropriate/Inadequate Shock/Stimulation																
6032	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance									
							F2203	Imaging Required	A072201	High Impedance									
6033	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem									
							F26	No Health Consequences or Impact	A05	Mechanical Problem									
6034	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem									
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem									
6035	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	14/08/2025	14/08/2025							
									A070504	Premature Discharge of Battery	14/08/2025	14/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/08/2025	14/08/2025							
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	14/08/2025	14/08/2025							
									A070504	Premature Discharge of Battery	14/08/2025	14/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/08/2025	14/08/2025							
6036	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			F1905	Device Revision or Replacement	A0705	Battery Problem	14/08/2025	14/08/2025							
									A070504	Premature Discharge of Battery	14/08/2025	14/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	14/08/2025	14/08/2025							
							CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem							
									F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings							
									A0705	Battery Problem									
6036																			

					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0705	Battery Problem		
8937	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
8938	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A072201	High Impedance		
							F17	Sedation	A072201	High Impedance		
							F22	Unexpected Diagnostic Intervention	A072201	High Impedance		
8939	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8940	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8941	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		

					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8942	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F2203	Imaging Required	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
8943	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
8944	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
						F2203	Imaging Required	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
8945	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/10/2025	09/10/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/10/2025	09/10/2025
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/10/2025	09/10/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/10/2025	09/10/2025
						F1903	Device Explanation	A070504	Premature Discharge of Battery	09/10/2025	09/10/2025	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/10/2025	09/10/2025
8946	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2303	Medication Required	A0709	Device Sensing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2303	Medication Required	A0709	Device Sensing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
						F2307	Reprogramming of Device	A0709	Device Sensing Problem			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8947	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A090801	Signal Artifact/Noise		
						F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm			
									A071302	Inappropriate/Inadequate Shock/Stimulation		

										A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)		A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A090801	Signal Artifact/Noise		
							F15	Recognized Device or Procedural Complication		A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)		A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A090801	Signal Artifact/Noise		
							F15	Recognized Device or Procedural Complication		A071201	Failure to Convert Rhythm		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072201	High Impedance		
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A090801	Signal Artifact/Noise		
8948	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia		A0709	Device Sensing Problem		
							E210401	Shock from Patient Lead(s)		A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury		A0709	Device Sensing Problem		
							F2307	Reprogramming of Device		A0709	Device Sensing Problem		
					CT1150	Defibrillators	E060109	Tachycardia		A0709	Device Sensing Problem		
							E210401	Shock from Patient Lead(s)		A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury		A0709	Device Sensing Problem		
							F2307	Reprogramming of Device		A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E060109	Tachycardia		A0709	Device Sensing Problem		
							E210401	Shock from Patient Lead(s)		A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury		A0709	Device Sensing Problem		
							F2307	Reprogramming of Device		A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E060109	Tachycardia		A0709	Device Sensing Problem		
							E210401	Shock from Patient Lead(s)		A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury		A0709	Device Sensing Problem		
							F2307	Reprogramming of Device		A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia		A0709	Device Sensing Problem		
							E210401	Shock from Patient Lead(s)		A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury		A0709	Device Sensing Problem		
							F2307	Reprogramming of Device		A0709	Device Sensing Problem		
8949	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact		A0709	Device Sensing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact		A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact		A0709	Device Sensing Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions		A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact		A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact		A0709	Device Sensing Problem		
8950	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing		
8951	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0601	Arrhythmia		A070910	Undersensing		
										A071202	Inaccurate Synchronization		
										A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing		
										A071202	Inaccurate Synchronization		
										A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	E0601	Arrhythmia		A070910	Undersensing		
										A071202	Inaccurate Synchronization		
										A1301	Failure to Read Input Signal		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A1301	Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A1301	Failure to Read Input Signal		
8952	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F26	No Health Consequences or Impact	A070101	Failure to Capture		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F26	No Health Consequences or Impact	A070101	Failure to Capture		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
							F26	No Health Consequences or Impact	A070101	Failure to Capture		
8953	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F12	Serious Injury/Illness/ Impairment	A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F12	Serious Injury/Illness/ Impairment	A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F12	Serious Injury/Illness/ Impairment	A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F12	Serious Injury/Illness/ Impairment	A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F12	Serious Injury/Illness/ Impairment	A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
8954	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
8955	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F1905	Device Revision or Replacement	A160602	Premature End-of-Life Indicator		
8956	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A0712	Pacing Problem		
							F1001	Absence of Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
8957	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
8958	2025		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E011903	Syncope/Fainting	A0706	Charging Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							E0601	Arrhythmia	A0706	Charging Problem		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A0706	Charging Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT1150	Defibrillators	E011903	Syncope/Fainting	A0706	Charging Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							E0601	Arrhythmia	A0706	Charging Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F02	Death	A0706	Charging Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	E011903	Syncope/Fainting	A0706	Charging Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							E0601	Arrhythmia	A0706	Charging Problem		

							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
									A0706	Charging Problem		
					CT263	Cardiographs and associated devices	E011903	Syncope/Fainting	A071301	Failure to Deliver Shock/Stimulation		
							E0601	Arrhythmia	A0706	Charging Problem		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E011903	Syncope/Fainting	A071301	Failure to Deliver Shock/Stimulation		
							E0601	Arrhythmia	A0706	Charging Problem		
							F02	Death	A071301	Failure to Deliver Shock/Stimulation		
8959	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071301	Failure to Deliver Shock/Stimulation		
							F2203	Imaging Required	A010402	Migration		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F2203	Imaging Required	A010402	Migration		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F2203	Imaging Required	A010402	Migration		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F2203	Imaging Required	A010402	Migration		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration		
							F2203	Imaging Required	A010402	Migration		
8960	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
8961	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0601	Arrhythmia	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
8962	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A070910	Undersensing		
									A0722	Impedance Problem		
							F26	No Health Consequences or Impact	A070101	Failure to Capture		
									A070910	Undersensing		
									A0722	Impedance Problem		
8963	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings		
							F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings		
							F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings		
							F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings		
							F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings		
							F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings		
8964	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	08/08/2025	08/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/08/2025	08/08/2025
							F1905	Device Revision or Replacement	A070504	Battery Problem	08/08/2025	08/08/2025
									A0705	Premature Discharge of Battery	08/08/2025	08/08/2025
8965	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	08/08/2025	08/08/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
8966	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/07/2025	11/07/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
									A0705	Battery Problem	11/07/2025	11/07/2025
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
									A0705	Battery Problem	11/07/2025	11/07/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	11/07/2025	11/07/2025

							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	11/07/2025	11/07/2025
									A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
									A0705	Battery Problem	11/07/2025	11/07/2025
6967	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A070504	Premature Discharge of Battery	11/07/2025	11/07/2025
									A0709	Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A0712	Pacing Problem		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
6968	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	28/08/2025	28/08/2025
									A0722	Impedance Problem	28/08/2025	28/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025	28/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	28/08/2025	28/08/2025
									A0722	Impedance Problem	28/08/2025	28/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025	28/08/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	28/08/2025	28/08/2025
									A0722	Impedance Problem	28/08/2025	28/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025	28/08/2025
6969	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
									A23	Use of Device Problem		
							F12	Serious Injury/ Illness/ Impairment	A13	Communication or Transmission Problem		
									A23	Use of Device Problem		
							F2307	Reprogramming of Device	A13	Communication or Transmission Problem		
									A23	Use of Device Problem		
6970	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A180601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A180601	Premature Elective Replacement Indicator		
6971	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/09/2025	18/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/09/2025	18/09/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2025	18/09/2025
6972	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0709	Device Sensing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0709	Device Sensing Problem		
6973	2025		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A25	No Apparent Adverse Event		
							F26	No Health Consequences or Impact	A25	No Apparent Adverse Event		
6974	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	05/08/2025	05/08/2025
									A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	05/08/2025	05/08/2025
							E24					

								F08		Hospitalization or Prolonged Hospitalization	A0908 A0705 A070504 A0908	Incorrect, Inadequate or Imprecise Result or Readings Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025 28/08/2025
								F1905		Device Revision or Replacement	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025
					CT1263		Cardiographs and associated devices	E2403		No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025
								F08		Hospitalization or Prolonged Hospitalization	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025
								F1905		Device Revision or Replacement	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025
					CT12866		Implantable cardiac electrical stimulators	E2403		No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025
								F08		Hospitalization or Prolonged Hospitalization	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025
								F1905		Device Revision or Replacement	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025
6982	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT11150	Defibrillators		E2403		No Clinical Signs, Symptoms or Conditions	A0705 A070504 A0908	Battery Problem Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	28/08/2025 28/08/2025 28/08/2025	28/08/2025 28/08/2025 28/08/2025
					CT1258	Implantable defibrillators		F1901		Additional Surgery	A070504	Premature Discharge of Battery	07/07/2025	07/07/2025
								E2403		No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2025	07/07/2025
								F1901		Additional Surgery	A070504	Premature Discharge of Battery	07/07/2025	07/07/2025
					CT12866	Implantable cardiac electrical stimulators		E2403		No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	07/07/2025	07/07/2025
6983	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT11150	Defibrillators		F1901		Additional Surgery	A070504	Premature Discharge of Battery	07/07/2025	07/07/2025
								E2403		No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								P26		No Health Consequences or Impact	A0712	Pacing Problem		
					CT1258	Implantable defibrillators		E2403		No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								P26		No Health Consequences or Impact	A0712	Pacing Problem		
								E2403		No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT12866	Implantable cardiac electrical stimulators		P26		No Health Consequences or Impact	A0712	Pacing Problem		
6984	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403		No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								P26		No Health Consequences or Impact	A0712	Pacing Problem		
								E2403		No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								P26		No Health Consequences or Impact	A0712	Pacing Problem		
6985	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators		E2403		No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	19/05/2025	19/05/2025
								F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
6986	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators		E2403		No Clinical Signs, Symptoms or Conditions	A1205	Loose or Intermittent Connection	17/07/2025	17/07/2025
								F1901		Additional Surgery	A1205	Loose or Intermittent Connection	17/07/2025	17/07/2025
6987	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators		E2401		Insufficient Information	A071301	Failure to Deliver Shock/Stimulation		
								F24		Insufficient Health Impact Information	A071301	Failure to Deliver Shock/Stimulation		
6988	2025	Death	37265	Dual-chamber implantable defibrillator	CT11150	Defibrillators		E020201		Anxiety	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E210401		Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E233001		Chest Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F02		Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08		Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1258	Implantable defibrillators		E020201		Anxiety	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E210401		Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
								E233001		Chest Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F02		Death	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F08		Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
6989	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators		E2403		No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
6990	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators		E2403		No Clinical Signs, Symptoms or Conditions	A070101 A070910 A0712	Failure to Capture Undersensing Pacing Problem		
								F10		Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101 A070910 A0712	Failure to Capture Undersensing Pacing Problem		
								F1001		Absence of Treatment	A070101 A070910 A0712	Failure to Capture Undersensing Pacing Problem		
								F15		Recognized Device or Procedural Complication	A070101 A070910 A0712	Failure to Capture Undersensing Pacing Problem		
6991	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators		E2403		No Clinical Signs, Symptoms or Conditions	A070909 A0712 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
								F08		Hospitalization or Prolonged Hospitalization	A070909 A0712 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
							F23	Unexpected Medical Intervention	A070909 A0712 A072201 A1301	Oversensing Pacing Problem High Impedance Failure to Read Input Signal		
8992	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
8993	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise	10/09/2025	10/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A1301 A070909 A090801	Failure to Read Input Signal Oversensing Signal Artifact/Noise	10/09/2025	10/09/2025
							F1905	Device Revision or Replacement	A1301 A070909 A090801	Failure to Read Input Signal Oversensing Signal Artifact/Noise	10/09/2025	10/09/2025
							F2203	Imaging Required	A1301 A070909 A090801	Failure to Read Input Signal Oversensing Signal Artifact/Noise	10/09/2025	10/09/2025
							F23	Unexpected Medical Intervention	A1301 A070909 A090801	Failure to Read Input Signal Oversensing Signal Artifact/Noise	10/09/2025	10/09/2025
8994	2025		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1301 A0705	Failure to Read Input Signal Battery Problem	10/09/2025	10/09/2025
8995	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
8996	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
8997	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712 A0709	Pacing Problem Device Sensing Problem		
8998	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0712 A072201	Pacing Problem High Impedance		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
8999	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0119	Loss of Consciousness	A070909 A071201 A0713 A072202 A090801 A0909	Oversensing Failure to Convert Rhythm Defibrillation/Stimulation Problem Low Impedance Signal Artifact/Noise Unexpected Therapeutic Results		
							E011903	Syncope/Fainting	A070909 A071201 A0713 A072202 A090801 A0909	Oversensing Failure to Convert Rhythm Defibrillation/Stimulation Problem Low Impedance Signal Artifact/Noise Unexpected Therapeutic Results		
							E2104	Electric Shock	A070909 A071201 A0713 A072202 A090801 A0909	Oversensing Failure to Convert Rhythm Defibrillation/Stimulation Problem Low Impedance Signal Artifact/Noise Unexpected Therapeutic Results		
							F05	Delay to Treatment/ Therapy	A070909 A071201 A0713 A072202 A090801 A0909	Oversensing Failure to Convert Rhythm Defibrillation/Stimulation Problem Low Impedance Signal Artifact/Noise Unexpected Therapeutic Results		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071201 A0713 A072202 A090801 A0909	Oversensing Failure to Convert Rhythm Defibrillation/Stimulation Problem Low Impedance Signal Artifact/Noise Unexpected Therapeutic Results		
							F1905	Device Revision or Replacement	A070909 A071201 A0713 A072202 A090801 A0909	Oversensing Failure to Convert Rhythm Defibrillation/Stimulation Problem Low Impedance Signal Artifact/Noise Unexpected Therapeutic Results		
7000	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025

7001	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
					CT2866	Implantable cardiac electrical stimulators	F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator	06/11/2025	06/11/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
7002	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	A071204		A071204	No Pacing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071204	No Pacing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
7003	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	F1905	Device Revision or Replacement	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
7004	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
							F1905	Device Revision or Replacement	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
					CT263	Cardiographs and associated devices	F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
							F1905	Device Revision or Replacement	A072201	High Impedance		
7005	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
							F1905	Device Revision or Replacement	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
7006	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
					CT258	Implantable defibrillators	F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
7007	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A040101	Fracture		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
7008	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	A1301		A1301	Failure to Read Input Signal		
									A070909	Oversensing		
7009	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	A071302		A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
					CT258	Implantable defibrillators	A090801		A071002	High Capture Threshold		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7010	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT258	Implantable defibrillators	A090801		A071002	High Capture Threshold		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	A071002		A071002	High Capture Threshold		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7011	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT258	Implantable defibrillators	A090801		A071002	High Capture Threshold		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		

7012	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F2203	Imaging Required	A070504	Premature Discharge of Battery	05/08/2025	05/08/2025
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
7013	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
7014	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7015	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F12	Serious Injury/Illness/Impairment	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
7016	2025		35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/09/2025	03/09/2025
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	03/09/2025	03/09/2025
7017	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT263	Cardiographs and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
7018	2025	Unanticipated serious deterioration in state of health	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0306	Sepsis	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							E1906	Unspecified Infection	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F1903	Device Explantation	A24	No Apparent Device Problem	09/07/2025	09/07/2025
					CT258	Implantable defibrillators	E0306	Sepsis	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							E1906	Unspecified Infection	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem	09/07/2025	09/07/2025

					CT2866	implantable cardiac electrical stimulators	F1903	Device Explanation	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							E0306	Sepsis	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F1906	Unspecified Infection	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem	09/07/2025	09/07/2025
							F1903	Device Explanation	A24	No Apparent Device Problem	09/07/2025	09/07/2025
7019	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
7020	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
7021	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7022	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A1107	Data Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
7023	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F1908	Prolonged Surgery	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F2306	Resuscitation	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
					CT1150	Defibrillators	E2104	Electric Shock	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F1908	Prolonged Surgery	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F2306	Resuscitation	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
					CT1258	Implantable defibrillators	E2104	Electric Shock	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F1908	Prolonged Surgery	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F2306	Resuscitation	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
					CT1263	Cardiographs and associated devices	E2104	Electric Shock	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F1908	Prolonged Surgery	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F2306	Resuscitation	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
					CT2866	implantable cardiac electrical stimulators	E2104	Electric Shock	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F1908	Prolonged Surgery	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
							F2306	Resuscitation	A071201	Failure to Convert Rhythm	29/07/2025	29/07/2025
7024	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		

							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F12	Serious Injury/ Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7025	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A070909	Oversensing		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F05	Delay to Treatment/ Therapy	A070909	Oversensing		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F1203	Life Threatening Illness or Injury	A070909	Oversensing		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A070910	Undersensing		
									A071202	Inaccurate Synchronization		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
7026	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7027	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
7028	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
					CT263	Cardiographs and associated devices	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		

							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
7029	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7030	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F23	Unexpected Medical Intervention	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F23	Unexpected Medical Intervention	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
							F23	Unexpected Medical Intervention	A070909	Oversensing	24/06/2025	24/06/2025
									A0712	Pacing Problem	24/06/2025	24/06/2025
									A072201	High Impedance	24/06/2025	24/06/2025
									A090801	Signal Artifact/Noise	24/06/2025	24/06/2025
									A1301	Failure to Read Input Signal	24/06/2025	24/06/2025
7031	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic	A0709	Device Sensing Problem		

									Exposure	A0712	Pacing Problem			
						F1203	Life Threatening Illness or Injury	A0709	Inappropriate/Inadequate Shock/Stimulation	A071302				
								A0712	Device Sensing Problem					
						F2307	Reprogramming of Device	A0712	Pacing Problem	A071302	Inappropriate/Inadequate Shock/Stimulation			
								A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem			
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F2307	Reprogramming of Device	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem			
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F2307	Reprogramming of Device	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem			
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F2307	Reprogramming of Device	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem			
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F2307	Reprogramming of Device	A0709	Device Sensing Problem					
								A0712	Pacing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
7032	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate				
							F26	No Health Consequences or Impact	A071102	Failure to Interrogate				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate				
							F26	No Health Consequences or Impact	A071102	Failure to Interrogate				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A071102	Failure to Interrogate				
							F26	No Health Consequences or Impact	A071102	Failure to Interrogate				
7033	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
7034	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture				
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture				
							F2303	Imaging Required	A070101	Failure to Capture				
7035	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem				
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
						F2307	Reprogramming of Device	A0709	Device Sensing Problem					
								A071302	Inappropriate/Inadequate Shock/Stimulation					
7036	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance				
							F26	No Health Consequences or Impact	A072201	High Impedance				
7037	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/09/2025		10/09/2025	
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/09/2025		10/09/2025	
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/09/2025		10/09/2025	
7038	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
								A070504	Premature Discharge of Battery					
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery				
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery				
7039	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070908	Oversensing				
								A090801	Signal Artifact/Noise					

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
7040	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A060801	Signal Artifact/Noise		
							F2203	Imaging Required	A070102	High Capture Threshold		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F2203	Imaging Required	A070102	High Capture Threshold		
									A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
									A072201	High Impedance		
							F2203	Imaging Required	A070102	High Capture Threshold		
									A072201	High Impedance		
7041	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
7042	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1905	Device Revision or Replacement	A160601	Premature Elective Replacement Indicator		
7043	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
									A1301	Failure to Read Input Signal		
7044	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem	25/09/2025	25/09/2025
									A072201	High Impedance	25/09/2025	25/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A13	Communication or Transmission Problem	25/09/2025	25/09/2025
									A0711	Interrogation Problem	25/09/2025	25/09/2025
									A072201	High Impedance	25/09/2025	25/09/2025
									A13	Communication or Transmission Problem	25/09/2025	25/09/2025
							F1905	Device Revision or Replacement	A0711	Interrogation Problem	25/09/2025	25/09/2025
									A072201	High Impedance	25/09/2025	25/09/2025
									A13	Communication or Transmission Problem	25/09/2025	25/09/2025
							F2203	Imaging Required	A0711	Interrogation Problem	25/09/2025	25/09/2025
									A072201	High Impedance	25/09/2025	25/09/2025
									A13	Communication or Transmission Problem	25/09/2025	25/09/2025
7045	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072001	Electromagnetic Interference		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
7046	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A071301	Failure to Deliver Shock/Stimulation		
							F1001	Absence of Treatment	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
7047	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
									A05	Mechanical Problem		
7048	2025		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2401	Insufficient Information	A0712	Pacing Problem		
							F19	Surgical Intervention	A07	Electrical /Electronic Property Problem		
					CT258	Implantable defibrillators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
							F19	Surgical Intervention	A07	Electrical /Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A07	Electrical /Electronic Property Problem		
							F19	Surgical Intervention	A07	Electrical /Electronic Property Problem		
7049	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060104	Bradycardia	A0712	Pacing Problem		
							F11	Non-Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
7050	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		

								F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
										A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
										A1301	Failure to Read Input Signal			
7051	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)		A0712	Pacing Problem			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation			
7052	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070602	Delayed Charge Time			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070910	Undersensing			
7053	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070602	Delayed Charge Time			
										A070910	Undersensing			
										A070102	High Capture Threshold			
										A070901	Decreased Sensitivity			
										A070909	Oversensing			
										A072001	Electromagnetic Interference			
							F26	No Health Consequences or Impact		A070102	High Capture Threshold			
										A070901	Decreased Sensitivity			
										A070909	Oversensing			
										A072001	Electromagnetic Interference			
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold			
										A070901	Decreased Sensitivity			
										A070909	Oversensing			
							F26	No Health Consequences or Impact		A070102	High Capture Threshold			
										A070901	Decreased Sensitivity			
										A070909	Oversensing			
										A072001	Electromagnetic Interference			
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold			
										A070901	Decreased Sensitivity			
										A070909	Oversensing			
							F26	No Health Consequences or Impact		A070102	High Capture Threshold			
										A070901	Decreased Sensitivity			
										A070909	Oversensing			
										A072001	Electromagnetic Interference			
7054	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A090805	Incorrect Measurement	01/08/2025	01/08/2025	
							F1901	Additional Surgery		A090805	Incorrect Measurement	01/08/2025	01/08/2025	
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A090805	Incorrect Measurement	01/08/2025	01/08/2025
							F1901	Additional Surgery		A090805	Incorrect Measurement	01/08/2025	01/08/2025	
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A090805	Incorrect Measurement	01/08/2025	01/08/2025
							F1901	Additional Surgery		A090805	Incorrect Measurement	01/08/2025	01/08/2025	
7055	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance			
							F26	No Health Consequences or Impact		A072201	High Impedance			
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance		
							F26	No Health Consequences or Impact		A072201	High Impedance			
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions		A072201	High Impedance		
							F26	No Health Consequences or Impact		A072201	High Impedance			
7056	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)		A070909	Oversensing			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
							F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
						CT1150	Defibrillators	E210401	Shock from Patient Lead(s)		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
							F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
						CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
							F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
						CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
							F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
						CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)		A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
							F2203	Imaging Required		A071302	Inappropriate/Inadequate Shock/Stimulation			
										A070909	Oversensing			
										A071302	Inappropriate/Inadequate Shock/Stimulation			
7057	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing			
										A0712	Pacing Problem			
										A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure		A070909	Oversensing			
										A0712	Pacing Problem			
										A1301	Failure to Read Input Signal			
						CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions		A070909	Oversensing		
										A0712	Pacing Problem			
										A1301	Failure to Read Input Signal			

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A1301	Oversensing Pacing Problem Failure to Read Input Signal		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A1301	Oversensing Pacing Problem Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A1301	Oversensing Pacing Problem Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A1301	Oversensing Pacing Problem Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A1301	Oversensing Pacing Problem Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A0712 A1301	Oversensing Pacing Problem Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A0712 A1301	Oversensing Pacing Problem Failure to Read Input Signal		
7058	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910 A071302	Oversensing Undersensing Inappropriate/Inadequate Shock/Stimulation		
7059	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7060	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		

					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
7061	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7062	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
7063	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0601	Arrhythmia	A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset		
					CT1150	Defibrillators	E0601	Arrhythmia	A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset		
					CT258	Implantable defibrillators	E0601	Arrhythmia	A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset		
					CT263	Cardiographs and associated devices	E0601	Arrhythmia	A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset		
					CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A160503	Inappropriate or Unexpected Reset		
							F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset		
7064	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1906	Unspecified Infection	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E1906	Unspecified Infection	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E1906	Unspecified Infection	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E1906	Unspecified Infection	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E1906	Unspecified Infection	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
7065	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A070909	Oversensing		

							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise			
									A0709	Device Sensing Problem			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
7066	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem			
									A070909	Oversensing			
									A090801	Signal Artifact/Noise			
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem			
									A070909	Oversensing			
7067	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
7068	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
									A090801	Signal Artifact/Noise			
							F2203	Imaging Required	A072201	High Impedance			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A072201	High Impedance			
									A090801	Signal Artifact/Noise			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
									A090801	Signal Artifact/Noise			
							F2203	Imaging Required	A072201	High Impedance			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A072201	High Impedance			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance			
									A090801	Signal Artifact/Noise			
							F2203	Imaging Required	A072201	High Impedance			
									A090801	Signal Artifact/Noise			
							F26	No Health Consequences or Impact	A072201	High Impedance			
7069	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A12	Connection Problem			
							F2203	Imaging Required	A12	Connection Problem			
7070	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
							A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	20/09/2024	20/09/2024	
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
					CT283	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
							F1905	Device Revision or Replacement	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024	
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	20/09/2024	20/09/2024	
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024	

							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024
									A0705	Battery Problem	20/09/2024	20/09/2024
									A070504	Premature Discharge of Battery	20/09/2024	20/09/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	20/09/2024	20/09/2024
7071	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
7072	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7073	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
7074	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
7075	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1304	Telemetry Discrepancy		
							F26	No Health Consequences or Impact	A1304	Telemetry Discrepancy		
7076	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
7077	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset		
									A1605	Reset Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
									A160503	Inappropriate or Unexpected Reset		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset		
									A1605	Reset Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A1605	Reset Problem		
							F26	No Health Consequences or Impact	A160503	Inappropriate or Unexpected Reset		
									A1605	Reset Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset		
							F26	No Health Consequences or Impact	A1605	Reset Problem		
									A160503	Inappropriate or Unexpected Reset		
7078	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A072202	Low Impedance		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A072202	Low Impedance		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A072202	Low Impedance		
7079	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7080	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		

					CT2866	Implantable cardiac electrical stimulators	E2403 F10	No Clinical Signs, Symptoms or Conditions Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070909	Oversensing Oversensing		
7081	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7082	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F1904	Device Repositioning	A1301	Failure to Read Input Signal		
							F1908	Prolonged Surgery	A1301	Failure to Read Input Signal		
							F23	Unexpected Medical Intervention	A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F1904	Device Repositioning	A1301	Failure to Read Input Signal		
7083	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	F1908	Prolonged Surgery	A1301	Failure to Read Input Signal		
							F23	Unexpected Medical Intervention	A1301	Failure to Read Input Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F1904	Device Repositioning	A1301	Failure to Read Input Signal		
							F1908	Prolonged Surgery	A1301	Failure to Read Input Signal		
							F23	Unexpected Medical Intervention	A1301	Failure to Read Input Signal		
7084	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/Illness/ Impairment	A070912	Incorrect Interpretation of Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/Illness/ Impairment	A070912	Incorrect Interpretation of Signal		
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070912	Incorrect Interpretation of Signal		
							F12	Serious Injury/Illness/ Impairment	A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
7085	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
7086	2025	All other reportable incidents	07265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
7087	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070910	Undersensing		
									A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A070910	Undersensing		
7088	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072202	Low Impedance		
							F26	No Health Consequences or Impact	A072202	Low Impedance		
7089	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
7090	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160601	Premature Elective Replacement Indicator		
7091	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	20/08/2025	20/08/2025
									A1301	Failure to Read Input Signal	20/08/2025	20/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	20/08/2025	20/08/2025
									A1301	Failure to Read Input Signal	20/08/2025	20/08/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	20/08/2025	20/08/2025
									A1301	Failure to Read Input Signal	20/08/2025	20/08/2025
7092	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/06/2025	11/06/2025
							F08	Hospitalization or Prolonged Hospitalization	A1107	Data Problem	11/06/2025	11/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/06/2025	11/06/2025
							F1905	Device Revision or Replacement	A1107	Data Problem	11/06/2025	11/06/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/06/2025	11/06/2025
7093	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F26	No Health Consequences or Impact	A060801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
7094	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A060801	Signal Artifact/Noise		
							F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
									A0909	Unexpected Therapeutic Results		
7095	2025	All other reportable incidents	97265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7096	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
7097	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E011903	Syncope/Fainting	A070910	Undersensing	04/09/2025	04/09/2025
									A0909	Unexpected Therapeutic Results	04/09/2025	04/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal	04/09/2025	04/09/2025
									A070910	Undersensing	04/09/2025	04/09/2025
									A0909	Unexpected Therapeutic Results	04/09/2025	04/09/2025
							F1001	Absence of Treatment	A1301	Failure to Read Input Signal	04/09/2025	04/09/2025
									A070910	Undersensing	04/09/2025	04/09/2025
									A0909	Unexpected Therapeutic Results	04/09/2025	04/09/2025
							F1905	Device Revision or Replacement	A1301	Failure to Read Input Signal	04/09/2025	04/09/2025
									A070910	Undersensing	04/09/2025	04/09/2025
									A0909	Unexpected Therapeutic Results	04/09/2025	04/09/2025
							F2203	Imaging Required	A1301	Failure to Read Input Signal	04/09/2025	04/09/2025
									A0909	Unexpected Therapeutic Results	04/09/2025	04/09/2025
									A1301	Failure to Read Input Signal	04/09/2025	04/09/2025
7098	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing	12/11/2025	12/11/2025
									A071302	Inappropriate/Inadequate Shock/Stimulation	12/11/2025	12/11/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	12/11/2025	12/11/2025
									A071302	Inappropriate/Inadequate Shock/Stimulation	12/11/2025	12/11/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	12/11/2025	12/11/2025
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	12/11/2025	12/11/2025
									A070909	Oversensing	12/11/2025	12/11/2025
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation	12/11/2025	12/11/2025
									A070909	Oversensing	12/11/2025	12/11/2025
									A071302	Inappropriate/Inadequate Shock/Stimulation	12/11/2025	12/11/2025
7099	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	04/09/2025	04/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/09/2025	04/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	04/09/2025	04/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/09/2025	04/09/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	04/09/2025	04/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	04/09/2025	04/09/2025
7100	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2025	25/11/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2025	25/11/2025

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/11/2025	25/11/2025
7101	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A0508	Noise, Audible		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A072201	High Impedance		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7102	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7103	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2115	Post Operative Wound Infection	A24	No Apparent Device Problem		
							F23	Unexpected Medical Intervention	A24	No Apparent Device Problem		
							F2303	Medication Required	A24	No Apparent Device Problem		
7104	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7105	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7106	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060104	Bradycardia	A070103	Intermittent Capture		
							F26	No Health Consequences or Impact	A070103	Intermittent Capture		
				CT1150	Defibrillators		E060104	Bradycardia	A070103	Intermittent Capture		
							F26	No Health Consequences or Impact	A070103	Intermittent Capture		
				CT258	Implantable defibrillators		E060104	Bradycardia	A070103	Intermittent Capture		
							F26	No Health Consequences or Impact	A070103	Intermittent Capture		
				CT263	Cardiographs and associated devices		E060104	Bradycardia	A070103	Intermittent Capture		
							F26	No Health Consequences or Impact	A070103	Intermittent Capture		
				CT2866	Implantable cardiac electrical stimulators		E060104	Bradycardia	A070103	Intermittent Capture		
							F26	No Health Consequences or Impact	A070103	Intermittent Capture		
7107	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7108	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7109	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic	A070909	Oversensing		

								Exposure	A071302 A090801 A1301	Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
7110	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7111	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	28/08/2025	28/08/2025
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	28/08/2025	28/08/2025
									A1301	Failure to Read Input Signal	28/08/2025	28/08/2025
									A1301	Failure to Read Input Signal	28/08/2025	28/08/2025
							F1901	Additional Surgery	A0709	Device Sensing Problem	28/08/2025	28/08/2025
									A1301	Failure to Read Input Signal	28/08/2025	28/08/2025
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	28/08/2025	28/08/2025
									A1301	Failure to Read Input Signal	28/08/2025	28/08/2025
7112	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070910 A071302 A1301	Undersensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910 A071302 A1301	Undersensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
7113	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							E2311	Discomfort	A0712	Pacing Problem		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							E2311	Discomfort	A0712	Pacing Problem		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							E2311	Discomfort	A0712	Pacing Problem		
							E2330	Pain	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302 A1301	Pacing Problem Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
7114	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
7115	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709 A071302 A0709	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation Device Sensing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
7116	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A090805	Incorrect Measurement		
							F26	No Health Consequences or Impact	A090805	Incorrect Measurement		
7117	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings	18/12/2025	18/12/2025
7118	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			F08	Hospitalization or Prolonged Hospitalization	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	18/12/2025	18/12/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/12/2025	18/12/2025
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	18/12/2025	18/12/2025
7119	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	03/09/2025	03/09/2025
							F26	No Health Consequences or Impact	A05	Mechanical Problem	03/09/2025	03/09/2025
7120	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E060109	Tachycardia	A0709 A0713	Device Sensing Problem Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F05	Delay to Treatment/ Therapy	A0709 A0713	Device Sensing Problem Defibrillation/Stimulation Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709 A0713	Device Sensing Problem Defibrillation/Stimulation Problem		

								F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
										A0709	Device Sensing Problem		
										A0713	Defibrillation/Stimulation Problem		
										A071301	Failure to Deliver Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A0713	Defibrillation/Stimulation Problem		
										A071301	Failure to Deliver Shock/Stimulation		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
										A0713	Defibrillation/Stimulation Problem		
										A071301	Failure to Deliver Shock/Stimulation		
7121	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E060110	Ventricular Fibrillation	A071202	Inaccurate Synchronization		
										A090801	Signal Artifact/Noise		
								F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization		
										A090801	Signal Artifact/Noise		
								F15	Recognized Device or Procedural Complication	A071202	Inaccurate Synchronization		
										A090801	Signal Artifact/Noise		
7122	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	21/10/2025	21/10/2025
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2025	21/10/2025
										A070504	Premature Discharge of Battery	21/10/2025	21/10/2025
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2025	21/10/2025
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	21/10/2025	21/10/2025
										A0908	Incorrect, Inadequate or Imprecise Result or Readings	21/10/2025	21/10/2025
7123	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A0722	Impedance Problem		
										A072201	High Impedance		
										A090801	Signal Artifact/Noise		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A0722	Impedance Problem		
										A072201	High Impedance		
										A090801	Signal Artifact/Noise		
7124	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
7125	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F12	Serious Injury/ Illness/ Impairment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
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										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
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										A071302	Inappropriate/Inadequate Shock/Stimulation		
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										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
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										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
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							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT2906	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
7128	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504 A0908	Noise, Audible Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0508 A070504 A0908	Noise, Audible Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
7129	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	08/12/2025	08/12/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	08/12/2025	08/12/2025
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	08/12/2025	08/12/2025
7130	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	20/10/2025	20/10/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	20/10/2025	20/10/2025
							F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	20/10/2025	20/10/2025
7131	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F08	Hospitalization or Prolonged Hospitalization	A23 A0709 A070909 A071302 A1301	Use of Device Problem Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A23 A0709	Use of Device Problem Device Sensing Problem		

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							F1903	Device Explanation	A070504	Premature Discharge of Battery	03/02/2026	03/02/2026
7138	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/02/2026	03/02/2026
									A070909	Overensing		
							F1001	Absence of Treatment	A0712	Pacing Problem		
									A070909	Overensing		
7139	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7140	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Overensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7141	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7142	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A1107	Data Problem		
									A23	Use of Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing		
									A1107	Data Problem		
									A23	Use of Device Problem		
							F2203	Imaging Required	A070909	Overensing		
									A1107	Data Problem		
							F23	Unexpected Medical Intervention	A23	Use of Device Problem		
									A070909	Overensing		
									A1107	Data Problem		
									A23	Use of Device Problem		
7143	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A1601	Device Alarm System		
7144	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
7145	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7146	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7147	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	23/09/2025	23/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/09/2025	23/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	23/09/2025	23/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/09/2025	23/09/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	23/09/2025	23/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/09/2025	23/09/2025
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation	23/09/2025	23/09/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/09/2025	23/09/2025
7148	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E0601	Arrhythmia	A070910	Underensing		
							F26	No Health Consequences or Impact	A070910	Underensing		
7149	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A070910	Underensing		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Overensing		
									A070910	Underensing		
									A090801	Signal Artifact/Noise		
7150	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Overensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7151	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		

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7155	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A1301	Failure to Read Input Signal								
										A070909	Oversensing								
										A070910	Undersensing								
										A071302	Inappropriate/Inadequate Shock/Stimulation								
								F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise								
										A070909	Oversensing								
										A070910	Undersensing								
										A071302	Inappropriate/Inadequate Shock/Stimulation								
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise								
										A070909	Oversensing								
										A070910	Undersensing								
										A071302	Inappropriate/Inadequate Shock/Stimulation								
								F2203	Imaging Required	A090801	Signal Artifact/Noise								
										A070909	Oversensing								
										A070910	Undersensing								
										A071302	Inappropriate/Inadequate Shock/Stimulation								
7156	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation									
									A072201	High Impedance									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
									A072201	High Impedance									
7157	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing									
									A072001	Electromagnetic Interference									
							F26	No Health Consequences or Impact	A070909	Oversensing									
									A072001	Electromagnetic Interference									
7158	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	10/11/2025	10/11/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/11/2025	10/11/2025							
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	10/11/2025	10/11/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/11/2025	10/11/2025							
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	10/11/2025	10/11/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	10/11/2025	10/11/2025							
							E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
7159	2025	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
							F02	Death	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
							CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2025	18/08/2025					
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025					
									F02	Death	A0705	Battery Problem	18/08/2025	18/08/2025					
											A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025					
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
							F02	Death	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
							F02	Death	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
							F02	Death	A0705	Battery Problem	18/08/2025	18/08/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	18/08/2025	18/08/2025							
7160	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
							F1001	Absence of Treatment	A0712	Pacing Problem									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
							7161	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
																A071302	Inappropriate/Inadequate Shock/Stimulation		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem																
		A071302	Inappropriate/Inadequate Shock/Stimulation																
7162	2025		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	18/09/2025								
									A070504	Premature Discharge of Battery	18/09/2025								
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	18/09/2025								
									A070504	Premature Discharge of Battery	18/09/2025								
F1903	Device Explanation	A070504	Premature Discharge of Battery	18/09/2025															
		A070504	Premature Discharge of Battery	18/09/2025															
F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/09/2025															
		A070504	Premature Discharge of Battery	18/09/2025															
7163	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
							F2307	Reprogramming of Device	A0709	Device Sensing Problem									
									A071302	Inappropriate/Inadequate Shock/Stimulation									
							E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture									
									A070910	Undersensing									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem									
									A070101	Failure to Capture									
F15	Recognized Device or Procedural Complication	A070910	Undersensing																
		A0712	Pacing Problem																
7164	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture							
											A070910	Undersensing							
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem							
											A070101	Failure to Capture							
									F15	Recognized Device or Procedural Complication	A070910	Undersensing							
											A0712	Pacing Problem							
							CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture							
											A070910	Undersensing							
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture							
											A070910	Undersensing							
							F15	Recognized Device or Procedural Complication	A0712	Pacing Problem									
									A070101	Failure to Capture									

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	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
							CT1150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
									E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
							CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
									E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
							CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
									E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
							CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery									
									E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery									
							7177	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem				
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing																		
		A071302	Inappropriate/Inadequate Shock/Stimulation																		
		A090801	Signal Artifact/Noise																		
		A1301	Failure to Read Input Signal																		
		A0709	Device Sensing Problem																		
		A070909	Oversensing																		
		A071302	Inappropriate/Inadequate Shock/Stimulation																		
		A090801	Signal Artifact/Noise																		
		A1301	Failure to Read Input Signal																		
		7178	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing									
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure								A090801	Signal Artifact/Noise											
									A070909	Oversensing											
									A090801	Signal Artifact/Noise											
									A070909	Oversensing											
									A090801	Signal Artifact/Noise											
									F2203	Imaging Required	A070909	Oversensing									
									A090801	Signal Artifact/Noise											
									7179	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E0712	Cough	A24	No Apparent Device Problem		
																E0731	Pleural Effusion	A24	No Apparent Device Problem		
		E1906	Unspecified Infection	A24	No Apparent Device Problem																
E233001	Chest Pain	A24	No Apparent Device Problem																		
F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem																		
F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem																		
F2303	Medication Required	A24	No Apparent Device Problem																		
7180	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E0112	Dizziness								A070909	Oversensing				
							E0623	Unspecified Heart Problem								A070910	Undersensing				
																A071302	Inappropriate/Inadequate Shock/Stimulation				
									A090801	Signal Artifact/Noise											
									E210401	Shock from Patient Lead(s)	A070909	Oversensing									
									A070910	Undersensing											
									A071302	Inappropriate/Inadequate Shock/Stimulation											
									A090801	Signal Artifact/Noise											
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing									
											A070910	Undersensing									
A071302	Inappropriate/Inadequate Shock/Stimulation																				
A090801	Signal Artifact/Noise																				
7181	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions			A070504	Premature Discharge of Battery	24/10/2025	24/10/2025							
							F08	Hospitalization or Prolonged Hospitalization			A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/10/2025	24/10/2025							
									A070504	Premature Discharge of Battery	24/10/2025	24/10/2025									
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/10/2025	24/10/2025									
									A070504	Premature Discharge of Battery	24/10/2025	24/10/2025									
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/10/2025	24/10/2025									
									F1903	Device Explantation	A070504	Premature Discharge of Battery	24/10/2025	24/10/2025							
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	24/10/2025	24/10/2025									
									A072201	High Impedance											
									F26	No Health Consequences or Impact	A072201	High Impedance									
7182	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator					E020201	Anxiety	A070909	Oversensing									
							E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation											
									A090801	Signal Artifact/Noise											
									A1301	Failure to Read Input Signal											
									A070909	Oversensing											
									A071302	Inappropriate/Inadequate Shock/Stimulation											
									A090801	Signal Artifact/Noise											
									A1301	Failure to Read Input Signal											
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing									
											A071302	Inappropriate/Inadequate Shock/Stimulation									
A090801	Signal Artifact/Noise																				
A1301	Failure to Read Input Signal																				
7183	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)			A070909	Oversensing									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A071302	Inappropriate/Inadequate Shock/Stimulation									
									A090801	Signal Artifact/Noise											
									A1301	Failure to Read Input Signal											
									A070909	Oversensing											
									A071302	Inappropriate/Inadequate Shock/Stimulation											
									A090801	Signal Artifact/Noise											
									A23	Use of Device Problem											
									A070909	Oversensing											
									A071302	Inappropriate/Inadequate Shock/Stimulation											
7184	2025	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator					CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing							
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation											
									A090801	Signal Artifact/Noise											
									A23	Use of Device Problem											
									A070909	Oversensing											
									A071302	Inappropriate/Inadequate Shock/Stimulation											
									A090801	Signal Artifact/Noise											
									A23	Use of Device Problem											
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing											
									A071302	Inappropriate/Inadequate Shock/Stimulation											
A090801	Signal Artifact/Noise																				
7185	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing									
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation											
									A090801	Signal Artifact/Noise											
									A23	Use of Device Problem											
									A070909	Oversensing											
							CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing									
											A071302	Inappropriate/Inadequate Shock/Stimulation									
											A090801	Signal Artifact/Noise									
											A23	Use of Device Problem									
											A070909	Oversensing									
A071302	Inappropriate/Inadequate Shock/Stimulation																				

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A23	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Use of Device Problem		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909 A071302 A090801 A23	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A23	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Use of Device Problem		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909 A071302 A090801 A23	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801 A23	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Use of Device Problem		
7185	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0713 A0908	Premature Discharge of Battery Defibrillation/Stimulation Problem Incorrect, Inadequate or Imprecise Result or Readings	18/11/2025 18/11/2025 18/11/2025	18/11/2025 18/11/2025 18/11/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504 A0713 A0908	Premature Discharge of Battery Defibrillation/Stimulation Problem Incorrect, Inadequate or Imprecise Result or Readings	18/11/2025 18/11/2025 18/11/2025	18/11/2025 18/11/2025 18/11/2025
							F1905	Device Revision or Replacement	A070504 A0713 A0908	Premature Discharge of Battery Defibrillation/Stimulation Problem Incorrect, Inadequate or Imprecise Result or Readings	18/11/2025 18/11/2025 18/11/2025	18/11/2025 18/11/2025 18/11/2025
7186	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072201	Oversensing High Impedance		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A072201	Oversensing High Impedance		
							F2203	Imaging Required	A070909 A072201	Oversensing High Impedance		
7187	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
7188	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT2866	implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
7189	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	01/01/2026	01/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	01/01/2026	01/01/2026
7190	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	01/01/2026	01/01/2026
							E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
7191	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
					CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0711	Interrogation Problem		
							F26	No Health Consequences or Impact	A0711	Interrogation Problem		
7192	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E0601	Arrhythmia	A0705 A0709	Battery Problem Device Sensing Problem		
							E210401	Shock from Patient Lead(s)	A071302 A0705 A0709 A071302	Inappropriate/Inadequate Shock/Stimulation Battery Problem Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0705 A0709 A071302	Battery Problem Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0705 A0709 A071302	Battery Problem Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0705 A0709 A071302	Battery Problem Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0705 A0709 A071302	Battery Problem Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
7193	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		

							F2203	Imaging Required	A072201	High Impedance		
7194	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/10/2025	17/10/2025
							F1901	Additional Surgery	A070504	Premature Discharge of Battery	17/10/2025	17/10/2025
7195	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F08	Hospitalization or Prolonged Hospitalization	A1205	Loose or Intermittent Connection		
									A0722	Impedance Problem		
									A072201	High Impedance		
							F12	Serious Injury/ Illness/ Impairment	A1205	Loose or Intermittent Connection		
									A0722	Impedance Problem		
									A072201	High Impedance		
							F1905	Device Revision or Replacement	A1205	Loose or Intermittent Connection		
									A0722	Impedance Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A1205	Loose or Intermittent Connection		
									A0722	Impedance Problem		
									A072201	High Impedance		
									A1205	Loose or Intermittent Connection		
7196	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
					CT258	Implantable defibrillators	F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator		
							E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator		
7197	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7198	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070602	Delayed Charge Time		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070602	Delayed Charge Time		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7199	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7200	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A072201	High Impedance		
									A072202	Low Impedance		
							F1001	Absence of Treatment	A070101	Failure to Capture		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A072201	High Impedance		
									A072202	Low Impedance		
7201	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2025	19/11/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2025	19/11/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/11/2025	19/11/2025
7202	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
7203	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	19/11/2025	19/11/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	19/11/2025	19/11/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	19/11/2025	19/11/2025
7204	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
7205	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
7206	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E060109	Tachycardia	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071301	Failure to Deliver Shock/Stimulation		
7207	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7208	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2002	Swine/Custody	A1605	Reset Problem		
							F12	Serious Injury/ Illness/ Impairment	A1605	Reset Problem		
							F2307	Reprogramming of Device	A1605	Reset Problem		
7209	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E060110	Ventricular Fibrillation	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F05	Delay to Treatment/ Therapy	A070909	Oversensing		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071202	Inaccurate Synchronization		
							F1006	Inadequate Treatment/Disease Progression	A070909	Oversensing		
									A070910	Undersensing		

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							F23	Unexpected Medical Intervention	A070909 A071204 A0709 A070909 A071204	Oversensing No Pacing Device Sensing Problem Oversensing No Pacing		
7225	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709 A0712	Device Sensing Problem Pacing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709 A0712	Device Sensing Problem Pacing Problem		
							F2307	Reprogramming of Device	A0709 A0712	Device Sensing Problem Pacing Problem		
7226	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/09/2025	23/09/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/09/2025	23/09/2025
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	23/09/2025	23/09/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/09/2025	23/09/2025
7227	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E0601	Arrhythmia	A070504	Premature Discharge of Battery	10/11/2025	10/11/2025
							F1901	Additional Surgery	A071102 A070504	Failure to Interrogate Premature Discharge of Battery	10/11/2025 10/11/2025	10/11/2025 10/11/2025
									A071102	Failure to interrogate	10/11/2025	10/11/2025
7228	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072001 A090801	Electromagnetic Interference Signal Artifact/Noise		
							F12	Serious injury/ illness/ impairment	A072001 A090801	Electromagnetic Interference Signal Artifact/Noise		
							F2307	Reprogramming of Device	A072001 A090801	Electromagnetic Interference Signal Artifact/Noise		
7229	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/10/2025	25/10/2025
							F08	Hospitalization or Prolonged Hospitalization	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	25/10/2025 25/10/2025	25/10/2025 25/10/2025
							F1905	Device Revision or Replacement	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	25/10/2025 25/10/2025	25/10/2025 25/10/2025
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	25/10/2025	25/10/2025
7230	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7231	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7232	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
							F26	No Health Consequences or Impact	A13	Communication or Transmission Problem		
7233	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A13	Communication or Transmission Problem		
							F26	No Health Consequences or Impact	A13	Communication or Transmission Problem		
7234	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2402	Appropriate Clinical Signs, Symptoms and Conditions Term/Code not Available	A24	No Apparent Device Problem		
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem		
							F1203	Life Threatening Illness or Injury	A24	No Apparent Device Problem		
							F2306	Resuscitation	A24	No Apparent Device Problem		
							F2307	Reprogramming of Device	A24	No Apparent Device Problem		
7235	2025	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT1258	Implantable defibrillators	E011903	Syncope/Fainting	A071201	Failure to Convert Rhythm		
							E0601	Arrhythmia	A071201	Failure to Convert Rhythm		
							F12	Serious Injury/ Illness/ Impairment	A071201	Failure to Convert Rhythm		
7236	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909 A071302 A090801	Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302 A090801	Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302 A090801	Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise		
							F2203	Imaging Required	A070909 A071302 A090801	Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise		
							F23	Unexpected Medical Intervention	A070909 A071302 A090801	Oversensing Inappropriate/inadequate Shock/Stimulation Signal Artifact/Noise		
7237	2025		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F1905	Device Revision or Replacement	A0705	Battery Problem		
					CT1286	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
							F1905	Device Revision or Replacement	A0705	Battery Problem		
7238	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery		
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
7239	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	08/11/2025	08/11/2025
							F08	Hospitalization or Prolonged Hospitalization	A05	Mechanical Problem	08/11/2025	08/11/2025
							F12	Serious Injury/ Illness/ Impairment	A05	Mechanical Problem	08/11/2025	08/11/2025
							F1905	Device Revision or Replacement	A05	Mechanical Problem	08/11/2025	08/11/2025
7240	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7241	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise	08/10/2025 08/10/2025	08/10/2025 08/10/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801	Oversensing Signal Artifact/Noise	08/10/2025 08/10/2025	08/10/2025 08/10/2025
							F1905	Device Revision or Replacement	A070909 A090801	Oversensing Signal Artifact/Noise	08/10/2025 08/10/2025	08/10/2025 08/10/2025
					CT11150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801	Oversensing Signal Artifact/Noise	08/10/2025 08/10/2025	08/10/2025 08/10/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	08/10/2025	08/10/2025

							F1905	Device Revision or Replacement	A070909	Oversensing	08/10/2025	08/10/2025
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise	08/10/2025	08/10/2025
									A070909	Oversensing	08/10/2025	08/10/2025
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	08/10/2025	08/10/2025
									A070909	Oversensing	08/10/2025	08/10/2025
							F1905	Device Revision or Replacement	A090801	Signal Artifact/Noise	08/10/2025	08/10/2025
									A070909	Oversensing	08/10/2025	08/10/2025
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	08/10/2025	08/10/2025
									A090801	Signal Artifact/Noise	08/10/2025	08/10/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	08/10/2025	08/10/2025
									A090801	Signal Artifact/Noise	08/10/2025	08/10/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	08/10/2025	08/10/2025
									A090801	Signal Artifact/Noise	08/10/2025	08/10/2025
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	08/10/2025	08/10/2025
									A090801	Signal Artifact/Noise	08/10/2025	08/10/2025
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	08/10/2025	08/10/2025
									A090801	Signal Artifact/Noise	08/10/2025	08/10/2025
							F1905	Device Revision or Replacement	A070909	Oversensing	08/10/2025	08/10/2025
									A070909	Oversensing	08/10/2025	08/10/2025
7242	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7243	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070101	Failure to Capture	11/12/2025	11/12/2025
									A0709	Device Sensing Problem	11/12/2025	11/12/2025
							F08	Hospitalization or Prolonged Hospitalization	A070101	Failure to Capture	11/12/2025	11/12/2025
									A0709	Device Sensing Problem	11/12/2025	11/12/2025
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture	11/12/2025	11/12/2025
									A0709	Device Sensing Problem	11/12/2025	11/12/2025
							F1203	Life Threatening Illness or Injury	A070101	Failure to Capture	11/12/2025	11/12/2025
									A0709	Device Sensing Problem	11/12/2025	11/12/2025
							F1905	Device Revision or Replacement	A070101	Failure to Capture	11/12/2025	11/12/2025
									A0709	Device Sensing Problem	11/12/2025	11/12/2025
7244	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/11/2025	05/11/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/11/2025	05/11/2025
							F17	Sedation	A070504	Premature Discharge of Battery	05/11/2025	05/11/2025
							F23	Unexpected Medical Intervention	A070504	Premature Discharge of Battery	05/11/2025	05/11/2025
7245	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
7246	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
7247	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7248	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	17/12/2025	17/12/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	17/12/2025	17/12/2025
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	17/12/2025	17/12/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	17/12/2025	17/12/2025
7249	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7250	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	18/11/2025	18/11/2025
							F26	No Health Consequences or Impact	A05	Mechanical Problem	18/11/2025	18/11/2025
7251	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A160105	False Alarm		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
									A160105	False Alarm		
7252	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909	Device Sensing Problem		
									A071302	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7253	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F26	No Health Consequences or Impact	A071302	Inappropriate/Inadequate Shock/Stimulation		
7254	2020	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070603	Failure to Charge	18/11/2020	18/11/2020
							F1901	Additional Surgery	A070603	Failure to Charge	18/11/2020	18/11/2020
7255	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	05/05/2023	05/05/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/05/2023	05/05/2023
							F12	Serious Injury/ Illness/ Impairment	A07	Electrical /Electronic Property Problem	05/05/2023	05/05/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/05/2023	05/05/2023
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	05/05/2023	05/05/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/05/2023	05/05/2023
							F12	Serious Injury/ Illness/ Impairment	A070604	Electrical /Electronic Property Problem	05/05/2023	05/05/2023
							F1905	Device Revision or Replacement	A07	Electrical /Electronic Property Problem	05/05/2023	05/05/2023
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	05/05/2023	05/05/2023
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/05/2023	05/05/2023
							F12	Serious Injury/ Illness/ Impairment	A07	Electrical /Electronic Property Problem	05/05/2023	05/05/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/05/2023	05/05/2023
7256	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A07	Electrical /Electronic Property Problem	05/05/2023	05/05/2023
							F08	Hospitalization or Prolonged Hospitalization	A070604	Premature Discharge of Battery	05/05/2023	05/05/2023
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
									A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
							F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
									A070504	Premature Discharge of Battery	23/04/2024	23/04/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	23/04/2024	23/04/2024
7257	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7258	2025		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0723	Unexpected Mode Switch		
							F01	Change in Therapeutic Response	A0909	Unexpected Therapeutic Results		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0723	Unexpected Mode Switch		
							F01	Change in Therapeutic Response	A0909	Unexpected Therapeutic Results		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0723	Unexpected Mode Switch		
							F01	Change in Therapeutic Response	A0909	Unexpected Therapeutic Results		
									A0723	Unexpected Mode Switch		
									A0909	Unexpected Therapeutic Results		
7259	2021	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	05/01/2022	05/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
							F1903	Device Explanation	A070909	Oversensing	05/01/2022	05/01/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022

					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	05/01/2022	05/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
							F1903	Device Explanation	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	05/01/2022	05/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
							F1903	Device Explanation	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	05/01/2022	05/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
							F1903	Device Explanation	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	05/01/2022	05/01/2022
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
							F1903	Device Explanation	A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
									A070909	Oversensing	05/01/2022	05/01/2022
									A071302	Inappropriate/Inadequate Shock/Stimulation	05/01/2022	05/01/2022
7260	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
					CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
7261	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem	24/04/2023	24/04/2023
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	24/04/2023	24/04/2023	
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	24/04/2023	24/04/2023	
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
						F1905	Device Revision or Replacement	A0709	Device Sensing Problem	24/04/2023	24/04/2023	
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
						F2203	Imaging Required	A0709	Device Sensing Problem	24/04/2023	24/04/2023	
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem	24/04/2023	24/04/2023
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
						F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	24/04/2023	24/04/2023	
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	24/04/2023	24/04/2023	
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
						F1905	Device Revision or Replacement	A0709	Device Sensing Problem	24/04/2023	24/04/2023	
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023

								F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023
				CT258	Implantable defibrillators	E2104	Electric Shock	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F1905	Device Revision or Replacement	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
				CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F1905	Device Revision or Replacement	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
				CT2866	implantable cardiac electrical stimulators	E2104	Electric Shock	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302 A090801	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise	24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F1905	Device Revision or Replacement	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
						F2203	Imaging Required	A0709 A070909 A071302 A090801 A1301	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	24/04/2023 24/04/2023 24/04/2023 24/04/2023 24/04/2023	
7262	2017	All other reportable incidents			CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A07 A0708	Electrical/Electronic Property Problem Power Problem	24/04/2023	24/04/2023	
7263	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available			
						F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available				
						F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available				
					CT1150	Defibrillators	E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available			
						F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available				
						F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available				
					CT258	implantable defibrillators	E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available			

7264	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
							F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available		
							E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
							F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available		
							E060102	Atrial Fibrillation	A27	Appropriate Device Problem Term/Code not Available		
					CT1150	Defibrillators	F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
							F23	Unexpected Medical Intervention	A27	Appropriate Device Problem Term/Code not Available		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
							F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
									A070504	Premature Discharge of Battery	11/02/2024	11/02/2024
							F1903	Device Explanation	A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024
CT258	Implantable defibrillators			A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
		E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
		F1903	Device Explanation	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
CT263	Cardiographs and associated devices			A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
		E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
		F1903	Device Explanation	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
CT2866	Implantable cardiac electrical stimulators			A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
		E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
		F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
		F1903	Device Explanation	A070504	Premature Discharge of Battery	11/02/2024	11/02/2024					
				A0908	Incorrect, Inadequate or Imprecise Result or Readings	11/02/2024	11/02/2024					
7265	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A1107	Data Problem		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A1107	Data Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A1107	Data Problem		
					CT1150	Defibrillators	F26	No Health Consequences or Impact	A072201	High Impedance		
									A1107	Data Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A1107	Data Problem		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A1107	Data Problem		
CT258	Implantable defibrillators			A072201	High Impedance							
		E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem							
		F26	No Health Consequences or Impact	A072201	High Impedance							
				A1107	Data Problem							
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
				A1107	Data Problem							
CT263	Cardiographs and associated devices			A072201	High Impedance							
		E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem							
		F26	No Health Consequences or Impact	A072201	High Impedance							
				A1107	Data Problem							
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
				A1107	Data Problem							
CT2866	Implantable cardiac electrical stimulators			A072201	High Impedance							
		E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem							
		F26	No Health Consequences or Impact	A072201	High Impedance							
				A1107	Data Problem							
		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance							
				A1107	Data Problem							
7266	2024	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070910	Undersensing		
									A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070910	Undersensing							
				A0712	Pacing Problem							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation							
				A070910	Undersensing							
				A0712	Pacing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070910	Undersensing							
				A0712	Pacing Problem							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation							
				A070910	Undersensing							
				A0712	Pacing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070910	Undersensing							
				A0712	Pacing Problem							
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation							
				A070910	Undersensing							
				A0712	Pacing Problem							
				A071302	Inappropriate/Inadequate Shock/Stimulation							
7267	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/02/2024	05/02/2024

						F08	Hospitalization or Prolonged Hospitalization	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	05/02/2024	05/02/2024	
						F1903	Device Explanation	A0908 A070504	Incorrect, Inadequate or Imprecise Result or Readings Premature Discharge of Battery	05/02/2024	05/02/2024	
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024
						F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024	
						F1903	Device Explanation	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024	
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024
						F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024	
						F1903	Device Explanation	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024	
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024
						F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024	
						F1903	Device Explanation	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024
						F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024	
						F1903	Device Explanation	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	05/02/2024	05/02/2024	
7268	2024		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0202 A0203 A0705	Defective Component Defective Device Battery Problem		
						F1903	Device Explanation	A0202 A0203 A0705	Defective Component Defective Device Battery Problem			
						F26	No Health Consequences or Impact	A0202 A0203 A0705	Defective Component Defective Device Battery Problem			
7269	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E060109	Tachycardia	A0701	Capturing Problem		
						E060110	Ventricular Fibrillation	A0701	Capturing Problem			
						F1203	Life Threatening Illness or Injury	A0701	Capturing Problem			
7270	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	04/02/2025	04/02/2025
						F08	Hospitalization or Prolonged Hospitalization	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	04/02/2025	04/02/2025	
						F1905	Device Revision or Replacement	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings	04/02/2025	04/02/2025	
7271	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT1150	Defibrillators	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
						F10	Inadequate/inappropriate Treatment or Diagnostic Exposure	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation			
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709 A070909 A071302	Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A0709 A070909	Device Sensing Problem Oversensing			

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									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
					F2203	Imaging Required			A0709	Device Sensing Problem	24/04/2023	24/04/2023
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem	24/04/2023	24/04/2023
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
					F08	Hospitalization or Prolonged Hospitalization			A0709	Device Sensing Problem	24/04/2023	24/04/2023
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0709	Device Sensing Problem	24/04/2023	24/04/2023
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
					F1905	Device Revision or Replacement			A0709	Device Sensing Problem	24/04/2023	24/04/2023
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
					F2203	Imaging Required			A0709	Device Sensing Problem	24/04/2023	24/04/2023
									A070909	Oversensing	24/04/2023	24/04/2023
									A071302	Inappropriate/Inadequate Shock/Stimulation	24/04/2023	24/04/2023
									A090801	Signal Artifact/Noise	24/04/2023	24/04/2023
									A1301	Failure to Read Input Signal	24/04/2023	24/04/2023
7278	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT11010	Cardiovascular physiology analysis/mapping devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E2104	Electric Shock	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7279	2024	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	25/04/2024	25/04/2024
							F08	Hospitalization or Prolonged Hospitalization	A05	Mechanical Problem	25/04/2024	25/04/2024
							F12	Serious Injury/ Illness/ Impairment	A05	Mechanical Problem	25/04/2024	25/04/2024
							F1905	Device Revision or Replacement	A05	Mechanical Problem	25/04/2024	25/04/2024
7280	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7281	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7282	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
7283	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
7284	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	08/01/2026	08/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	08/01/2026	08/01/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	08/01/2026	08/01/2026
7285	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem	18/12/2025	18/12/2025
							F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem	18/12/2025	18/12/2025
							F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem	18/12/2025	18/12/2025
							F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem	18/12/2025	18/12/2025
7286	2025		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0102	Brain Injury	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
							F02	Death	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
					CT1150	Defibrillators	E0102	Brain Injury	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
							F02	Death	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
					CT258	Implantable defibrillators	E0102	Brain Injury	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
							F02	Death	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
					CT263	Cardiographs and associated devices	E0102	Brain Injury	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
							F02	Death	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
					CT2866	Implantable cardiac electrical stimulators	E0102	Brain Injury	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
							F02	Death	A0105	Lack of Effect		
									A0203	Defective Device		
									A0713	Defibrillation/Stimulation Problem		
									A0721	Circuit Failure		
7287	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A072201	High Impedance		
									A070909	Oversensing		
7288	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							P26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7289	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0101	Patient-Device Incompatibility		
									A071201	Failure to Convert Rhythm		
							F1908	Prolonged Surgery	A0101	Patient-Device Incompatibility		
									A071201	Failure to Convert Rhythm		
							P23	Unexpected Medical Intervention	A0101	Patient-Device Incompatibility		
									A071201	Failure to Convert Rhythm		
7290	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7291	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A12	Connection Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A12	Connection Problem		
7292	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
7293	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7294	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2104	Electric Shock			
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure			
7295	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								F26	No Health Consequences or Impact	A072201	High Impedance	
7296	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
7297	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem	
								F2203	Imaging Required	A0709	Device Sensing Problem	
7298	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								F26	No Health Consequences or Impact	A072201	High Impedance	
7299	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/02/2026
								F08	Hospitalization or Prolonged Hospitalization	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/02/2026
								F1905	Device Revision or Replacement	A0908	Incorrect, Inadequate or Imprecise Result or Readings	27/02/2026
7300	2025	Death	35852	Single-chamber implantable defibrillator				E0133	Stroke/CVA	A070909	Oversensing	06/12/2025
									A0712	Pacing Problem	06/12/2025	06/12/2025
								E060101	Astysote	A070909	Oversensing	06/12/2025
									A0712	Pacing Problem	06/12/2025	06/12/2025
								F02	Death	A070909	Oversensing	06/12/2025
									A0712	Pacing Problem	06/12/2025	06/12/2025
								F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	06/12/2025
									A0712	Pacing Problem	06/12/2025	06/12/2025
								F1203	Life Threatening Illness or Injury	A070909	Oversensing	06/12/2025
									A0712	Pacing Problem	06/12/2025	06/12/2025
								F2306	Resuscitation	A070909	Oversensing	06/12/2025
									A0712	Pacing Problem	06/12/2025	06/12/2025
								F2307	Reprogramming of Device	A070909	Oversensing	06/12/2025
									A0712	Pacing Problem	06/12/2025	06/12/2025
7301	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
									A1301	Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
									A1301	Failure to Read Input Signal		
7302	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
									A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
									A0712	Pacing Problem		
7303	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	03/03/2026
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/03/2026	03/03/2026
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	03/03/2026
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/03/2026	03/03/2026
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	03/03/2026
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	03/03/2026	03/03/2026
7304	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7305	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7306	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A23	Use of Device Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A23	Use of Device Problem		
7307	2025		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1903	Device Explanation	A070504	Premature Discharge of Battery		
7308	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								F26	No Health Consequences or Impact	A072201	High Impedance	
7309	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
							F1903	Device Explanation	A160601	Premature Elective Replacement Indicator		

7310	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F1903	Device Explanation	A160601	Premature Elective Replacement Indicator			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F1903	Device Explanation	A160601	Premature Elective Replacement Indicator			
					CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F1903	Device Explanation	A160601	Premature Elective Replacement Indicator			
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F1903	Device Explanation	A160601	Premature Elective Replacement Indicator			
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F1903	Device Explanation	A160601	Premature Elective Replacement Indicator			
7311	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F1903	Device Explanation	A160601	Premature Elective Replacement Indicator			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F1903	Device Explanation	A160601	Premature Elective Replacement Indicator			
					CT1010	Cardiovascular physiology analysis/mapping devices	E060106	Heart Block	A07	Electrical /Electronic Property Problem		
						E0734	Pneumothorax	A07	Electrical /Electronic Property Problem			
						F08	Hospitalization or Prolonged Hospitalization	A07	Electrical /Electronic Property Problem			
						F1203	Life Threatening Illness or Injury	A07	Electrical /Electronic Property Problem			
					CT1150	Defibrillators	E060106	Heart Block	A07	Electrical /Electronic Property Problem		
						E0734	Pneumothorax	A07	Electrical /Electronic Property Problem			
7312	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0112	Dizziness	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026
						E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026	
						F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026	
						F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026	
					CT258	Implantable defibrillators	F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026
							E0112	Dizziness	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026
							E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026
							F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026
						F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026	
						F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026	
CT2866	Implantable cardiac electrical stimulators	E0112	Dizziness	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026					
		E2403	No Clinical Signs, Symptoms or Conditions	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026					
		F08	Hospitalization or Prolonged Hospitalization	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026					
		F12	Serious Injury/ Illness/ Impairment	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026					
	F1905	Device Revision or Replacement	A0713	Defibrillation/Stimulation Problem	25/03/2026	25/03/2026						
7313	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070910	Undersensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation			
								A070910	Undersensing			
								A071302	Inappropriate/Inadequate Shock/Stimulation			
7314	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/12/2025	23/12/2025
								A1605	Reset Problem	23/12/2025	23/12/2025	
						F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/12/2025	23/12/2025	
						F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	23/12/2025	23/12/2025	
						F1905	Device Revision or Replacement	A0705	Battery Problem	23/12/2025	23/12/2025	
7315	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Reset Problem	23/12/2025	23/12/2025
								A090801	Signal Artifact/Noise			
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
								A090801	Signal Artifact/Noise			
7316	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			

7317	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/12/2025	30/12/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/12/2025	30/12/2025
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery	30/12/2025	30/12/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/12/2025	30/12/2025
7318	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Overensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F12	Serious Injury/ Illness/ Impairment	A070909	Overensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909	Overensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7319	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	10/12/2025	10/12/2025
									A0711	Interrogation Problem	10/12/2025	10/12/2025
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	10/12/2025	10/12/2025
									A0711	Interrogation Problem	10/12/2025	10/12/2025
							F1905	Device Revision or Replacement	A0705	Battery Problem	10/12/2025	10/12/2025
									A0711	Interrogation Problem	10/12/2025	10/12/2025
7320	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Overensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7321	2025	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Overensing		
									A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Overensing		
									A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7322	2025		37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F21	Unexpected Deterioration	A160601	Premature Elective Replacement Indicator		
									A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A160601	Premature Elective Replacement Indicator		
7323	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E020203	Distress	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							E2330	Pain	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7324	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation	15/02/2026	15/02/2026
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation	15/02/2026	15/02/2026
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation	15/02/2026	15/02/2026
7325	2025	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7326	2025		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F1901	Additional Surgery	A0722	Impedance Problem		
									A072201	High Impedance		
							F2301	Additional Device Required	A0722	Impedance Problem		
									A072201	High Impedance		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F1901	Additional Surgery	A0722	Impedance Problem		
									A072201	High Impedance		
							F2301	Additional Device Required	A0722	Impedance Problem		
									A072201	High Impedance		
					CT2806	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem		
									A072201	High Impedance		
							F1901	Additional Surgery	A0722	Impedance Problem		
									A072201	High Impedance		
							F2301	Additional Device Required	A0722	Impedance Problem		
									A072201	High Impedance		
7327	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801 A0709 A070909 A071302 A090801 A0709 A070909 A071302 A090801	Signal Artifact/Noise Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Device Sensing Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
							F2203	Imaging Required	A071302 A0712 A071302	Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
7328	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302 A0712 A071302	Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302 A0712 A071302	Inappropriate/Inadequate Shock/Stimulation Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
7329	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E011903	Syncope/Fainting	A070909 A070910 A070909 A070910	Oversensing Undersensing Oversensing Undersensing		
							F05	Delay to Treatment/ Therapy	A070909 A070910	Oversensing Undersensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A070910	Oversensing Undersensing		
							F11	Non-Serious Injury/ Illness/ Impairment	A070909 A070910	Oversensing Undersensing		
7330	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909 A071302	Oversensing Inappropriate/Inadequate Shock/Stimulation		
7331	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A072001	Electromagnetic Interference		
							F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
7332	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070912 A071302	Incorrect Interpretation of Signal Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A070912 A071302	Incorrect Interpretation of Signal Inappropriate/Inadequate Shock/Stimulation		
7333	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705 A0711	Battery Problem Interrogation Problem	09/03/2026 09/03/2026	09/03/2026 09/03/2026
							F08	Hospitalization or Prolonged Hospitalization	A0705 A0711	Battery Problem Interrogation Problem	09/03/2026 09/03/2026	09/03/2026 09/03/2026
							F1903	Device Implantation	A0705 A0711	Battery Problem Interrogation Problem	09/03/2026 09/03/2026	09/03/2026 09/03/2026
7334	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070101 A070102	Failure to Capture High Capture Threshold		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101 A070102 A1301	Failure to Capture High Capture Threshold Failure to Read Input Signal		
7335	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909 A071302 A090801	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070909 A071302 A090801 A1301	Failure to Read Input Signal Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
7336	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0712 A071302	Pacing Problem Inappropriate/Inadequate Shock/Stimulation		
7337	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302 A071302	Inappropriate/Inadequate Shock/Stimulation Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
7338	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
							F23	Unexpected Medical Intervention	A071201	Failure to Convert Rhythm		
7339	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705 A071102	Battery Problem Failure to Interrogate	22/01/2026 22/01/2026	22/01/2026 22/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A0705 A071102	Battery Problem Failure to Interrogate	22/01/2026 22/01/2026	22/01/2026 22/01/2026
							F12	Serious Injury/ Illness/ Impairment	A0705 A071102	Battery Problem Failure to Interrogate	22/01/2026 22/01/2026	22/01/2026 22/01/2026
							F1905	Device Revision or Replacement	A0705 A071102	Battery Problem Failure to Interrogate	22/01/2026 22/01/2026	22/01/2026 22/01/2

									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7343	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	22/03/2026	22/03/2026
							F26	No Health Consequences or Impact	A070504	Incorrect, Inadequate or Imprecise Result or Readings	22/03/2026	22/03/2026
									A0908	Premature Discharge of Battery	22/03/2026	22/03/2026
7344	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Incorrect, Inadequate or Imprecise Result or Readings	22/03/2026	22/03/2026
									A071302	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Oversensing		
									A070909	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
7345	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7346	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Inappropriate/Inadequate Shock/Stimulation		
7347	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		
							F08	Hospitalization or Prolonged Hospitalization	A070910	Undersensing		
							F23	Unexpected Medical Intervention	A070910	Undersensing		
7348	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A090801	Signal Artifact/Noise		
									A070101	Failure to Capture		
									A070102	High Capture Threshold		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7349	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
7350	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E060110	Ventricular Fibrillation	A0101	Patient-Device Incompatibility		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
							F15	Recognized Device or Procedural Complication	A0722	Impedance Problem		
									A0101	Patient-Device Incompatibility		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
							F1904	Device Repositioning	A0101	Patient-Device Incompatibility		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
							F1908	Prolonged Surgery	A0101	Patient-Device Incompatibility		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
									A0722	Impedance Problem		
7351	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	13/03/2026	13/03/2026
									A070910	Undersensing	13/03/2026	13/03/2026
							F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	13/03/2026	13/03/2026
									A070909	Oversensing	13/03/2026	13/03/2026
									A070910	Undersensing	13/03/2026	13/03/2026
									A090801	Signal Artifact/Noise	13/03/2026	13/03/2026
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	13/03/2026	13/03/2026
									A070910	Undersensing	13/03/2026	13/03/2026
									A090801	Signal Artifact/Noise	13/03/2026	13/03/2026
							F1905	Device Revision or Replacement	A070909	Oversensing	13/03/2026	13/03/2026
									A070910	Undersensing	13/03/2026	13/03/2026
									A090801	Signal Artifact/Noise	13/03/2026	13/03/2026
7352	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	08/01/2026	08/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A05	Mechanical Problem	08/01/2026	08/01/2026
							F12	Serious Injury/ Illness/ Impairment	A05	Mechanical Problem	08/01/2026	08/01/2026
							F1905	Device Revision or Replacement	A05	Mechanical Problem	08/01/2026	08/01/2026

7353	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/inadequate Shock/Stimulation		
7354	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E020201	Anxiety	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A1106	Data Back-Up Problem		
							E0623	Unspecified Heart Problem	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A1106	Data Back-Up Problem		
							E210401	Shock from Patient Lead(s)	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A1106	Data Back-Up Problem		
							F08	Hospitalization or Prolonged Hospitalization	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A1106	Data Back-Up Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A1106	Data Back-Up Problem		
							F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm		
									A071302	Inappropriate/inadequate Shock/Stimulation		
									A1106	Data Back-Up Problem		
7355	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7356	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
7357	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
									A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A072201	High Impedance		
									A1301	Failure to Read Input Signal		
7358	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/inadequate Shock/Stimulation		
7359	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
7360	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F2303	Medication Required	A071302	Inappropriate/inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A071302	Inappropriate/inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A071302	Inappropriate/inadequate Shock/Stimulation		
7361	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7362	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7363	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							F1905	Device Revision or Replacement	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							F1905	Device Revision or Replacement	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							F1905	Device Revision or Replacement	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026
									A090801	Signal Artifact/Noise	16/01/2026	16/01/2026
							E2403	No Clinical Signs, Symptoms or Conditions	A010402	Migration	16/01/2026	16/01/2026
									A070909	Oversensing	16/01/2026	16/01/2026

						F08	Hospitalization or Prolonged Hospitalization	A090801 A010402 A070909 A090801	Signal Artifact/Noise Migration Oversensing Signal Artifact/Noise	16/01/2026 16/01/2026 16/01/2026 16/01/2026	16/01/2026 16/01/2026 16/01/2026 16/01/2026
						F1905	Device Revision or Replacement	A010402 A070909 A090801	Migration Oversensing Signal Artifact/Noise	16/01/2026 16/01/2026 16/01/2026	16/01/2026 16/01/2026 16/01/2026
				CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A010402 A070909 A090801	Migration Oversensing Signal Artifact/Noise	16/01/2026 16/01/2026 16/01/2026	16/01/2026 16/01/2026 16/01/2026
						F08	Hospitalization or Prolonged Hospitalization	A010402 A090801	Migration Oversensing Signal Artifact/Noise	16/01/2026 16/01/2026 16/01/2026	16/01/2026 16/01/2026 16/01/2026
						F1905	Device Revision or Replacement	A010402 A070909 A090801	Migration Oversensing Signal Artifact/Noise	16/01/2026 16/01/2026 16/01/2026	16/01/2026 16/01/2026 16/01/2026
7364	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact	A070504 A0908	Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
7365	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A072201	High Impedance		
7366	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
						F08	Hospitalization or Prolonged Hospitalization	A160601	Premature Elective Replacement Indicator		
7367	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
						F12	Serious Injury/Illness/Impairment	A0709	Device Sensing Problem		
7368	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		F2307	Reprogramming of Device	A0709	Device Sensing Problem		
						E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
						F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7369	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	27/03/2026	27/03/2026
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	27/03/2026	27/03/2026
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	27/03/2026	27/03/2026
7370	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
						F12	Serious Injury/Illness/Impairment	A0709	Device Sensing Problem		
						F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
7371	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F12	Serious Injury/Illness/Impairment	A070909	Oversensing		
						F2307	Reprogramming of Device	A070909	Oversensing		
7372	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070102 A070909 A072202	High Capture Threshold Oversensing Low Impedance		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A1301 A070102 A070909 A072202	Failure to Read Input Signal High Capture Threshold Oversensing Low Impedance		
						F2203	Imaging Required	A1301 A070102 A070909 A072202	Failure to Read Input Signal High Capture Threshold Oversensing Low Impedance		
7373	2026	Death	35852	Single-chamber implantable defibrillator		E2401	Insufficient Information	A070910 A090801	Undersensing Signal Artifact/Noise		
						F02	Death	A070910 A090801	Undersensing Signal Artifact/Noise		
7374	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	25/11/2025	25/11/2025
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	25/11/2025	25/11/2025
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	25/11/2025	25/11/2025
7375	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
						F26	No Health Consequences or Impact	A12 A072201	Connection Problem High Impedance		
7376	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E1906	Unspecified Infection	A24	No Apparent Device Problem	29/06/2022	29/06/2022
						F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	29/06/2022	29/06/2022
						F1905	Device Revision or Replacement	A24	No Apparent Device Problem	29/06/2022	29/06/2022
7377	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
						F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7378	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E210401	Shock from Patient Lead(s)	A070909 A071302 A090801 A1301	Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A23 A070909 A071302 A090801 A1301	Use of Device Problem Oversensing Inappropriate/Inadequate Shock/Stimulation Signal Artifact/Noise Failure to Read Input Signal		
7379	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E0402	Hypersensitivity/Allergic Reaction	A23	Use of Device Problem	01/06/2025	01/06/2025
						E1906	Unspecified Infection	A24	No Apparent Device Problem	01/06/2025	01/06/2025
						E2338	Swelling/ Edema	A24	No Apparent Device Problem	01/06/2025	01/06/2025
						F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	01/06/2025	01/06/2025
7380	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		F1905	Device Revision or Replacement	A24	No Apparent Device Problem	01/06/2025	01/06/2025
						E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
7381	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/05/2026	31/05/2026
						F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/05/2026	31/05/2026
						F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/05/2026	31/05/2026
7382	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
						F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0709	Device Sensing Problem		

								F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7383	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E060109	Tachycardia	A0709	Device Sensing Problem		
								F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
7384	2026		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E020201	Anxiety		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							E2403	No Clinical Signs, Symptoms or Conditions		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F1901	Additional Surgery		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F26	No Health Consequences or Impact		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
					CT1150	Defibrillators	E020201	Anxiety		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							E2403	No Clinical Signs, Symptoms or Conditions		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F1901	Additional Surgery		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F26	No Health Consequences or Impact		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
					CT258	Implantable defibrillators	E020201	Anxiety		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							E2403	No Clinical Signs, Symptoms or Conditions		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F1901	Additional Surgery		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F26	No Health Consequences or Impact		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
					CT263	Cardiographs and associated devices	E020201	Anxiety		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							E2403	No Clinical Signs, Symptoms or Conditions		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F1901	Additional Surgery		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F26	No Health Consequences or Impact		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
					CT2750	Implantable cardiac electrical stimulators and associated devices	E020201	Anxiety		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							E2403	No Clinical Signs, Symptoms or Conditions		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F1901	Additional Surgery		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F26	No Health Consequences or Impact		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
					CT2866	Implantable cardiac electrical stimulators	E020201	Anxiety		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							E2403	No Clinical Signs, Symptoms or Conditions		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F1901	Additional Surgery		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
							F26	No Health Consequences or Impact		A0711	Interrogation Problem		
										A2205	Device Provides Uninformative Message		
										A27	Appropriate Device Problem Term/Code not Available		
7385	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070904	Premature Discharge of Battery		
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery		
								F2307	Reprogramming of Device	A070504	Premature Discharge of Battery		
7386	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2104	Electric Shock	A071201	Failure to Convert Rhythm		
										A072201	High Impedance		
								F15	Recognized Device or Procedural Complication	A071201	Failure to Convert Rhythm		
										A072201	High Impedance		
								F2306	Resuscitation	A071201	Failure to Convert Rhythm		
										A072201	High Impedance		
7387	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A09	Output Problem		
										A090811	Unable to Obtain Readings		

								F12	Serious Injury/ Illness/ Impairment	A09	Output Problem		
								F2307	Reprogramming of Device	A090811	Unable to Obtain Readings		
								F26	No Health Consequences or Impact	A09	Output Problem		
								E2403	No Clinical Signs, Symptoms or Conditions	A090811	Unable to Obtain Readings		
7388	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				F26	No Health Consequences or Impact	A090811	Unable to Obtain Readings		
								E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	04/02/2026	04/02/2026
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise	04/02/2026	04/02/2026
								F26	No Health Consequences or Impact	A070909	Oversensing	04/02/2026	04/02/2026
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise	04/02/2026	04/02/2026
7389	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
								F26	No Health Consequences or Impact	A070909	Oversensing		
								F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
7390	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
7391	2026		37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	28/01/2026	28/01/2026
								F1901	Additional Surgery	A17	Compatibility Problem	28/01/2026	28/01/2026
								F1901	Additional Surgery	A160503	Inappropriate or Unexpected Reset	28/01/2026	28/01/2026
								F1901	Additional Surgery	A17	Compatibility Problem	28/01/2026	28/01/2026
7392	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2117	Twiddlers Syndrome		A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
								F2203	Imaging Required	A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
					CT1150	Defibrillators	E2117	Twiddlers Syndrome		A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
								F2203	Imaging Required	A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
					CT258	Implantable defibrillators	E2117	Twiddlers Syndrome		A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
								F2203	Imaging Required	A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
					CT263	Cardiographs and associated devices	E2117	Twiddlers Syndrome		A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
								F2203	Imaging Required	A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
								F2203	Imaging Required	A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
								F2203	Imaging Required	A072201	High Impedance		
								F2203	Imaging Required	A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A150202	Malposition of Device		
								F2203	Imaging Required	A23	Use of Device Problem		
7393	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E060109	Tachycardia	A0709	Device Sensing Problem		
								F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
7394	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
								F05	Delay to Treatment/ Therapy	A0713	Defibrillation/Stimulation Problem		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
								F1203	Life Threatening Illness or Injury	A0713	Defibrillation/Stimulation Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0713	Defibrillation/Stimulation Problem		
7395	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E060109	Tachycardia	A0709	Device Sensing Problem		
								F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A071301	Failure to Deliver Shock/Stimulation		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A071301	Failure to Deliver Shock/Stimulation		
7396	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7397	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	01/02/2026	01/02/2026
								F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	01/02/2026	01/02/2026
								F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	01/02/2026	01/02/2026
								F08	Hospitalization or Prolonged Hospitalization	A090801	Signal Artifact/Noise	01/02/2026	01/02/2026

								F1905	Device Revision or Replacement	A070909	Oversensing	01/02/2026	01/02/2026
								F2203	Imaging Required	A090801	Signal Artifact/Noise	01/02/2026	01/02/2026
										A070909	Oversensing	01/02/2026	01/02/2026
										A090801	Signal Artifact/Noise	01/02/2026	01/02/2026
7398	2026	Death	37265	Dual-chamber implantable defibrillator				E0601	Arrhythmia	A070910	Undersensing		
								F02	Death	A0713	Defibrillation/Stimulation Problem		
										A070910	Undersensing		
								F15	Recognized Device or Procedural Complication	A070910	Undersensing		
										A0713	Defibrillation/Stimulation Problem		
7399	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7400	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
								F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
7401	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A1107	Data Problem		
								F26	No Health Consequences or Impact	A1605	Reset Problem		
										A1107	Data Problem		
										A1605	Reset Problem		
7402	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing		
										A070910	Undersensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A070910	Undersensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7403	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
										A070909	Oversensing		
										A072201	High Impedance		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070101	Failure to Capture		
										A070909	Oversensing		
7404	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
										A072001	Electromagnetic Interference		
								F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
										A072001	Electromagnetic Interference		
										A090801	Signal Artifact/Noise		
7405	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem	06/02/2026	06/02/2026
								F26	No Health Consequences or Impact	A05	Mechanical Problem	06/02/2026	06/02/2026
7406	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070910	Undersensing		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A1301	Failure to Read Input Signal		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070910	Undersensing		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A1301	Failure to Read Input Signal		
7407	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1908	Prolonged Surgery	A071302	Inappropriate/Inadequate Shock/Stimulation		
7408	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0722	Impedance Problem	16/02/2026	16/02/2026
										A090801	Signal Artifact/Noise	16/02/2026	16/02/2026
								F08	Hospitalization or Prolonged Hospitalization	A0722	Impedance Problem	16/02/2026	16/02/2026
										A090801	Signal Artifact/Noise	16/02/2026	16/02/2026
								F1905	Device Revision or Replacement	A0722	Impedance Problem	16/02/2026	16/02/2026
										A090801	Signal Artifact/Noise	16/02/2026	16/02/2026
7409	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072001	Electromagnetic Interference		
										A090801	Signal Artifact/Noise		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072001	Electromagnetic Interference		
										A090801	Signal Artifact/Noise		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072001	Electromagnetic Interference		
										A090801	Signal Artifact/Noise		
7410	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A1301	Failure to Read Input Signal		
										A23	Use of Device Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A1301	Failure to Read Input Signal		
										A23	Use of Device Problem		
7411	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2311	Discomfort	A070909	Oversensing	19/02/2026	19/02/2026
								F26	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	19/02/2026	19/02/2026
								F12	Serious Injury/Illness/Impairment	A070909	Oversensing	19/02/2026	19/02/2026
								F1905	Device Revision or Replacement	A070909	Oversensing	19/02/2026	19/02/2026
7412	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
7413	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7414	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E0112	Dizziness	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								E060110	Ventricular Fibrillation	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								E2312	Fatigue	A0709	Device Sensing Problem		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A071302	Device Sensing Problem		
							F23	Unexpected Medical Intervention	A0709	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Device Sensing Problem		
7415	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1905	Device Revision or Replacement	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
7416	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
7417	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
7418	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F23	Unexpected Medical Intervention	A071302	Inappropriate/Inadequate Shock/Stimulation		
7419	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7420	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0712	Pacing Problem		
7421	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
7422	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
							F2303	Medication Required	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7423	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F12	Serious Injury/ Illness/ Impairment	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F23	Unexpected Medical Intervention	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7424	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
7425	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7426	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/02/2026	23/02/2026
							F08	Hospitalization or Prolonged Hospitalization	A07054	Premature Discharge of Battery	23/02/2026	23/02/2026
									A0705	Battery Problem	23/02/2026	23/02/2026
							F1905	Device Revision or Replacement	A07054	Premature Discharge of Battery	23/02/2026	23/02/2026
									A0705	Battery Problem	23/02/2026	23/02/2026
									A07054	Premature Discharge of Battery	23/02/2026	23/02/2026
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/02/2026	23/02/2026

								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/02/2026	23/02/2026
										A0705	Battery Problem	23/02/2026	23/02/2026
										A070504	Premature Discharge of Battery	23/02/2026	23/02/2026
								F1905	Device Revision or Replacement	A0705	Battery Problem	23/02/2026	23/02/2026
										A070504	Premature Discharge of Battery	23/02/2026	23/02/2026
								E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/02/2026	23/02/2026
										A070504	Premature Discharge of Battery	23/02/2026	23/02/2026
								F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/02/2026	23/02/2026
										A070504	Premature Discharge of Battery	23/02/2026	23/02/2026
								F1905	Device Revision or Replacement	A0705	Battery Problem	23/02/2026	23/02/2026
										A070504	Premature Discharge of Battery	23/02/2026	23/02/2026
7427	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A0705	Battery Problem		
7428	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F12	Serious Injury/Illness/ Impairment	A0709	Device Sensing Problem		
								F2307	Reprogramming of Device	A0709	Device Sensing Problem		
7429	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
								F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7430	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
7431	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A090801	Signal Artifact/Noise		
								F26	No Health Consequences or Impact	A070909	Oversensing		
										A090801	Signal Artifact/Noise		
7432	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7433	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
7434	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A1301	Failure to Read Input Signal		
								F26	No Health Consequences or Impact	A070909	Oversensing		
										A1301	Failure to Read Input Signal		
7435	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
7436	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
								F23	Unexpected Medical Intervention	A1301	Failure to Read Input Signal		
7437	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
								F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7438	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E060109	Tachycardia	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
7439	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E060109	Tachycardia	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F05	Delay to Treatment/ Therapy	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
7440	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7441	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
										A0722	Impedance Problem		
								F26	No Health Consequences or Impact	A072201	High Impedance		
										A05	Mechanical Problem		
										A0722	Impedance Problem		
7442	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F12	Serious Injury/Illness/ Impairment	A070504	Premature Discharge of Battery		
								F2307	Reprogramming of Device	A070504	Premature Discharge of Battery		
7443	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
										A072201	High Impedance		
										A0909	Unexpected Therapeutic Results		
								F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
										A072201	High Impedance		
										A0909	Unexpected Therapeutic Results		
										A071201	Failure to Convert Rhythm		
										A072201	High Impedance		
										A0909	Unexpected Therapeutic Results		
										A071201	Failure to Convert Rhythm		
										A072201	High Impedance		
										A0909	Unexpected Therapeutic Results		
7444	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/04/2021	09/04/2021
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/04/2021	09/04/2021
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	09/04/2021	09/04/2021

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						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					E060110	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					E0602	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					F02	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					F03	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					F0601	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					F10	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					F1203	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					F1204	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
					F21	A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
CT1150	Defibrillators	E0103	Cerebral Edema			A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			

		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
E0115	Encephalopathy	A0405	Degraded		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
E060110	Ventricular Fibrillation	A0405	Structural Problem		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
E0602	Cardiac Arrest	A0405	Structural Problem		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
F02	Death	A0405	Structural Problem		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
F03	Brain Death	A0405	Structural Problem		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
F0801	Intensive Care	A0405	Structural Problem		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0405	Structural Problem		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
F1203	Life Threatening Illness or Injury	A0405	Structural Problem		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
F1204	Permanent Impairment	A0405	Structural Problem		
		A0511	Structural Problem		
		A0710	Failure to Conduct		
		A071301	Failure to Deliver Shock/Stimulation		
		A072102	Electrical Shorting		
		A072202	Low Impedance		
		A090402	Failure to Deliver Energy		
		A090405	Output Below Specifications		
		A090406	Therapeutic or Diagnostic Output Failure		
		A0405	Degraded		
F21	Unexpected Deterioration	A0405	Degraded		
		A0511	Structural Problem		

						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
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						A072102	Electrical Shorting			
						A072202	Low Impedance			
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						A090406	Therapeutic or Diagnostic Output Failure			
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						A072102	Electrical Shorting			
						A072202	Low Impedance			
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						A0405	Degraded			
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						A072102	Electrical Shorting			
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						A072102	Electrical Shorting			
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						A072102	Electrical Shorting			
						A072202	Low Impedance			
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						A072102	Electrical Shorting			
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						A090406	Therapeutic or Diagnostic Output Failure			
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						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
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						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
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						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
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						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
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						A071301	Failure to Deliver Shock/Stimulation			
						A072102	Electrical Shorting			
						A072202	Low Impedance			
						A090402	Failure to Deliver Energy			
						A090405	Output Below Specifications			
						A090406	Therapeutic or Diagnostic Output Failure			
						A0405	Degraded			
						A0511	Structural Problem			
						A0710	Failure to Conduct			
						A071301	Failure to Deliver Shock			

						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		
			F21	Unexpected Deterioration		A0405	Degraded		
						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		
						A0405	Degraded		
						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		
						A0405	Degraded		
						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		
						A0405	Degraded		
						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		
						A0405	Degraded		
						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		
						A0405	Degraded		
						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		
						A0405	Degraded		
						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		
						A0405	Degraded		
						A0511	Structural Problem		
						A0710	Failure to Conduct		
						A071301	Failure to Deliver Shock/Stimulation		
						A072102	Electrical Shorting		
						A072202	Low Impedance		
						A090402	Failure to Deliver Energy		
						A090405	Output Below Specifications		
						A090406	Therapeutic or Diagnostic Output Failure		

						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0390406 A0405 A0511 A0710 A071301 A072102 A072202 A090402 A090405 A090406	Therapeutic or Diagnostic Output Failure Degraded Structural Problem Failure to Conduct Failure to Deliver Shock/Stimulation Electrical Shorting Low Impedance Failure to Deliver Energy Output Below Specifications Therapeutic or Diagnostic Output Failure		
						F1203	Life Threatening Illness or Injury	A0405 A0511 A0710 A071301 A072102 A072202 A090402 A090405 A090406	Degraded Structural Problem Failure to Conduct Failure to Deliver Shock/Stimulation Electrical Shorting Low Impedance Failure to Deliver Energy Output Below Specifications Therapeutic or Diagnostic Output Failure		
						F1204	Permanent Impairment	A0405 A0511 A0710 A071301 A072102 A072202 A090402 A090405 A090406	Degraded Structural Problem Failure to Conduct Failure to Deliver Shock/Stimulation Electrical Shorting Low Impedance Failure to Deliver Energy Output Below Specifications Therapeutic or Diagnostic Output Failure		
						F21	Unexpected Deterioration	A0405 A0511 A0710 A071301 A072102 A072202 A090402 A090405 A090406	Degraded Structural Problem Failure to Conduct Failure to Deliver Shock/Stimulation Electrical Shorting Low Impedance Failure to Deliver Energy Output Below Specifications Therapeutic or Diagnostic Output Failure		
7459	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E210401	Shock from Patient Lead(s)	A0390406 A0709 A071302	Therapeutic or Diagnostic Output Failure Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
						F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
7460	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001	Oversensing Electromagnetic Interference		
						F26	No Health Consequences or Impact	A070909 A072001	Oversensing Electromagnetic Interference		
7461	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
						F26	No Health Consequences or Impact	A070909	Oversensing		
7462	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A070909 A070910 A0712	Oversensing Undersensing Pacing Problem		
						F26	No Health Consequences or Impact	A070909 A070910 A0712	Oversensing Undersensing Pacing Problem		
7463	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A0709 A072001 A1702	Device Sensing Problem Electromagnetic Interference Device-Device Incompatibility		
						F12	Serious Injury/ Illness/ Impairment	A0709 A072001 A1702	Device Sensing Problem Electromagnetic Interference Device-Device Incompatibility		
						F2307	Reprogramming of Device	A0709 A072001 A1702	Device Sensing Problem Electromagnetic Interference Device-Device Incompatibility		
7464	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E210401	Shock from Patient Lead(s)	A070909 A071302 A072201	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance		
						F2203	Imaging Required	A070909 A071302 A072201	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance		
						F1009	Inappropriate Treatment	A070909 A071302 A072201	Oversensing Inappropriate/Inadequate Shock/Stimulation High Impedance		
7465	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A05 A1206	Mechanical Problem Misconnection	11/03/2026	11/03/2026
						F26	No Health Consequences or Impact	A05 A1206	Mechanical Problem Misconnection	11/03/2026	11/03/2026
7466	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator		E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
						F1009	Inappropriate Treatment	A0712	Pacing Problem		
						E060109	Tachycardia	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
						F08	Hospitalization or Prolonged Hospitalization	A0709 A071301	Device Sensing Problem Failure to Deliver Shock/Stimulation		
						F1001	Absence of Treatment	A0709	Device Sensing Problem		
						F1203	Life Threatening Illness or Injury	A071301 A0709	Failure to Deliver Shock/Stimulation Device Sensing Problem		
						F2307	Reprogramming of Device	A071301 A0709	Failure to Deliver Shock/Stimulation Device Sensing Problem		

7468	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A010402	Migration		
							A070909	Oversensing				
							A070910	Undersensing				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
							A072202	Low Impedance				
							A1301	Failure to Read Input Signal				
							F08	Hospitalization or Prolonged Hospitalization	A010402	Migration		
							A070909	Oversensing				
							A070910	Undersensing				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
							A072202	Low Impedance				
							A1301	Failure to Read Input Signal				
							F1905	Device Revision or Replacement	A010402	Migration		
							A070909	Oversensing				
							A070910	Undersensing				
							A071302	Inappropriate/Inadequate Shock/Stimulation				
							A072202	Low Impedance				
							A1301	Failure to Read Input Signal				
							F2203	Imaging Required	A010402	Migration		
							A070909	Oversensing				
							A070910	Undersensing				
A071302	Inappropriate/Inadequate Shock/Stimulation											
A072202	Low Impedance											
A1301	Failure to Read Input Signal											
F1009	Inappropriate Treatment	A010402	Migration									
A070909	Oversensing											
A070910	Undersensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A072202	Low Impedance											
A1301	Failure to Read Input Signal											
7469	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	04/03/2026	04/03/2026
							A070909	Oversensing	04/03/2026	04/03/2026		
							A071302	Inappropriate/Inadequate Shock/Stimulation	04/03/2026	04/03/2026		
							A090801	Signal Artifact/Noise	04/03/2026	04/03/2026		
							A1301	Failure to Read Input Signal	04/03/2026	04/03/2026		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	04/03/2026	04/03/2026
							A070909	Oversensing	04/03/2026	04/03/2026		
							A071302	Inappropriate/Inadequate Shock/Stimulation	04/03/2026	04/03/2026		
							A090801	Signal Artifact/Noise	04/03/2026	04/03/2026		
							A1301	Failure to Read Input Signal	04/03/2026	04/03/2026		
							F1905	Device Revision or Replacement	A0709	Device Sensing Problem	04/03/2026	04/03/2026
							A070909	Oversensing	04/03/2026	04/03/2026		
							A071302	Inappropriate/Inadequate Shock/Stimulation	04/03/2026	04/03/2026		
							A090801	Signal Artifact/Noise	04/03/2026	04/03/2026		
							A1301	Failure to Read Input Signal	04/03/2026	04/03/2026		
							F1009	Inappropriate Treatment	A0709	Device Sensing Problem	04/03/2026	04/03/2026
							A070909	Oversensing	04/03/2026	04/03/2026		
							A071302	Inappropriate/Inadequate Shock/Stimulation	04/03/2026	04/03/2026		
							A090801	Signal Artifact/Noise	04/03/2026	04/03/2026		
							A1301	Failure to Read Input Signal	04/03/2026	04/03/2026		
							7470	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010
A070909	Oversensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A1301	Failure to Read Input Signal											
F1009	Inappropriate Treatment	A23	Use of Device Problem									
A0709	Device Sensing Problem											
A070909	Oversensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A1301	Failure to Read Input Signal											
A23	Use of Device Problem											
CT1150	Defibrillators	E210401	Shock from Patient Lead(s)									
A0709	Device Sensing Problem											
A070909	Oversensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A1301	Failure to Read Input Signal											
A23	Use of Device Problem											
F1009	Inappropriate Treatment	A0709	Device Sensing Problem									
A070909	Oversensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A1301	Failure to Read Input Signal											
A23	Use of Device Problem											
CT1258	Implantable defibrillators	E210401	Shock from Patient Lead(s)									
A0709	Device Sensing Problem											
A070909	Oversensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A1301	Failure to Read Input Signal											
A23	Use of Device Problem											
F1009	Inappropriate Treatment	A0709	Device Sensing Problem									
A070909	Oversensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A1301	Failure to Read Input Signal											
A23	Use of Device Problem											
CT1263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)									
A0709	Device Sensing Problem											
A070909	Oversensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A1301	Failure to Read Input Signal											
A23	Use of Device Problem											
F1009	Inappropriate Treatment	A0709	Device Sensing Problem									
A070909	Oversensing											
A071302	Inappropriate/Inadequate Shock/Stimulation											
A1301	Failure to Read Input Signal											

					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A23	Use of Device Problem		
									A0709	Device Sensing Problem		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
							F1009	Inappropriate Treatment	A0709	Device Sensing Problem		
									A070909	Overensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
									A23	Use of Device Problem		
7471	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Overensing		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7472	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Overensing		
									A090801	Signal Artifact/Noise		
7473	2026	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
							F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									A1107	Data Problem		
7474	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
							F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
7475	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
7476	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A071302	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2303	Medication Required	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7477	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Overensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		

							F12	Serious Injury/ Illness/ Impairment	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F2307	Reprogramming of Device	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
7485	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E0112	Dizziness	A0709 A0712 A071302 A072001 A090801	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise		
							E060109	Tachycardia	A0709 A0712 A071302 A072001 A090801	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise		
							E060110	Ventricular Fibrillation	A0709 A0712 A071302 A072001 A090801	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise		
							E210401	Shock from Patient Lead(s)	A0709 A0712 A071302 A072001 A090801	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A0712 A071302 A072001 A090801	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise		
							F1203	Life Threatening Illness or Injury	A0709 A0712 A071302 A072001 A090801	Device Sensing Problem Pacing Problem Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference Signal Artifact/Noise		
7486	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0508 A070504 A0908	Noise, Audible Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0508 A070504 A0908	Noise, Audible Premature Discharge of Battery Incorrect, Inadequate or Imprecise Result or Readings		
7487	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
7488	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			F26	No Health Consequences or Impact	A072001	Electromagnetic Interference		
7489	2026	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator			E0505	Hematoma	A24	No Apparent Device Problem		
							F23	Unexpected Medical Intervention	A24	No Apparent Device Problem		
							E060106	Heart Block	A27	Appropriate Device Problem Term/Code not Available		
							F08	Hospitalization or Prolonged Hospitalization	A27	Appropriate Device Problem Term/Code not Available		
							F1203	Life Threatening Illness or Injury	A27	Appropriate Device Problem Term/Code not Available		
							F2303	Medication Required	A27	Appropriate Device Problem Term/Code not Available		
							F2306	Resuscitation	A27	Appropriate Device Problem Term/Code not Available		
7490	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909 A072001 A090801	Oversensing Electromagnetic Interference Signal Artifact/Noise		
7491	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070101 A072201 A1206	Failure to Capture High Impedance Misconnection		
							F12	Serious Injury/ Illness/ Impairment	A070101 A072201 A1206	Failure to Capture High Impedance Misconnection		
							F1905	Device Revision or Replacement	A070101 A072201	Failure to Capture High Impedance		
7492	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E060109	Tachycardia	A1206 A0709	Misconnection Device Sensing Problem		
							F05	Delay to Treatment/ Therapy	A071301 A0709	Failure to Deliver Shock/Stimulation Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071301 A0709	Failure to Deliver Shock/Stimulation Device Sensing Problem		
							F2307	Reprogramming of Device	A071301 A0709	Failure to Deliver Shock/Stimulation Device Sensing Problem		
7493	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
							F23	Unexpected Medical Intervention	A0709 A071302	Device Sensing Problem Inappropriate/Inadequate Shock/Stimulation		
7494	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709 A070909 A0712 A071302 A072001	Device Sensing Problem Oversensing Pacing Problem Inappropriate/Inadequate Shock/Stimulation Electromagnetic Interference		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709 A070909	Device Sensing Problem Oversensing		

										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072001	Electromagnetic Interference		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072001	Electromagnetic Interference		
								F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
										A070909	Oversensing		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A072001	Electromagnetic Interference		
7495	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
										A072001	Electromagnetic Interference		
								F26	No Health Consequences or Impact	A0712	Pacing Problem		
										A072001	Electromagnetic Interference		
7496	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F23	Unexpected Medical Intervention	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7497	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
										A070909	Oversensing		
								F26	No Health Consequences or Impact	A0705	Battery Problem		
										A070909	Oversensing		
7498	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
								F1009	Inappropriate Treatment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
7499	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
7500	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	31/03/2026	31/03/2026
								F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	31/03/2026	31/03/2026
								F12	Serious Injury/Illness/Impairment	A070504	Premature Discharge of Battery	31/03/2026	31/03/2026
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	31/03/2026	31/03/2026
7501	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7502	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072001	Electromagnetic Interference		
								F12	Serious Injury/Illness/Impairment	A072001	Electromagnetic Interference		
								F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
7503	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
7504	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
								F2203	Imaging Required	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
								F1009	Inappropriate Treatment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
7505	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
7506	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7507	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
										A072201	High Impedance		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A070909	Oversensing		
										A072201	High Impedance		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
								F26	No Health Consequences or Impact	A070909	Oversensing		
										A072201	High Impedance		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
7508	2026		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A0705	Battery Problem		
7509	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		

7510	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E0112	Dizziness	A0712	Pacing Problem	02/04/2026	02/04/2026
							E011902	Presyncope	A0712	Pacing Problem	02/04/2026	02/04/2026
							E060104	Bradycardia	A0712	Pacing Problem	02/04/2026	02/04/2026
							E060106	Heart Block	A0712	Pacing Problem	02/04/2026	02/04/2026
							F08	Hospitalization or Prolonged Hospitalization	A0712	Pacing Problem	02/04/2026	02/04/2026
7511	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			F1203	Life Threatening Illness or Injury	A0712	Pacing Problem	02/04/2026	02/04/2026
							F1905	Device Revision or Replacement	A0712	Pacing Problem	02/04/2026	02/04/2026
							E0112	Dizziness	A0712	Pacing Problem	02/04/2026	02/04/2026
							E0601	Arrhythmia	A0712	Pacing Problem		
							E083901	Blurred Vision	A0712	Pacing Problem		
7512	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			F12	Serious Injury/ Illness/ Impairment	A0712	Pacing Problem		
							F23	Unexpected Medical Intervention	A0712	Pacing Problem		
							E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
7513	2026		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator	26/02/2026	
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator	26/02/2026	
							F26	No Health Consequences or Impact	A160602	Premature End-of-Life Indicator	26/02/2026	
							E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7514	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
7515	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
7516	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E020201	Anxiety	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
									A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
					CT1150	Defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
									A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
					CT258	implantable defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
									A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
					CT263	Cardiographs and associated devices	E020201	Anxiety	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
									A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
					CT2866	Implantable cardiac electrical stimulators	E020201	Anxiety	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
									A070504	Premature Discharge of Battery	26/02/2025	26/02/2025
7517	2026		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A09	Output Problem		
									A160601	Premature Elective Replacement Indicator		
							F23	Unexpected Medical Intervention	A070504	Premature Discharge of Battery		
									A09	Output Problem		
									A160601	Premature Elective Replacement Indicator		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A09	Output Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A09	Output Problem		
									A160601	Premature Elective Replacement Indicator		
							F23	Unexpected Medical Intervention	A070504	Premature Discharge of Battery		
									A09	Output Problem		
									A160601	Premature Elective Replacement Indicator		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A09	Output Problem		
					CT2866	implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A09	Output Problem		
									A160601	Premature Elective Replacement Indicator		
							F23	Unexpected Medical Intervention	A070504	Premature Discharge of Battery		
									A09	Output Problem		
									A160601	Premature Elective Replacement Indicator		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A09	Output Problem		
7518	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070602	Delayed Charge Time		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A070602	Delayed Charge Time		
									A072201	High Impedance		
7519	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1901	Additional Surgery	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2307	Reprogramming of Device	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
7520	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A0709	Device Sensing Problem		
									A070909	Oversensing		
7520									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0709	Device Sensing Problem		

									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7521	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7522	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A1301	Failure to Read Input Signal		
							F2307	Reprogramming of Device	A1301	Failure to Read Input Signal		
7523	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A090801	Signal Artifact/Noise		
7524	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
7525	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E0618	Non Specific EKG/ECG Changes	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A070909	Oversensing		
									A0712	Pacing Problem		
									A072001	Electromagnetic Interference		
									A090801	Signal Artifact/Noise		
7526	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7527	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
7528	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0722	Impedance Problem		
									A090801	Signal Artifact/Noise		
							F1009	Inappropriate Treatment	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0722	Impedance Problem		
									A090801	Signal Artifact/Noise		
7529	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
7530	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7531	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A070909	Oversensing		

					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
7532	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060109	Tachycardia	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E060109	Tachycardia	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
7533	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F2203	Imaging Required	A070909	Oversensing		
7534	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A071204	No Pacing		
									A070909	Oversensing		
									A071204	No Pacing		
7535	2026	All other reportable incidents	47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
									A0722	Impedance Problem		
							F08	Hospitalization or Prolonged Hospitalization	A072201	High Impedance		
									A05	Mechanical Problem		
									A0722	Impedance Problem		
									A072201	High Impedance		
							F12	Serious Injury/ Illness/ Impairment	A05	Mechanical Problem		
									A0722	Impedance Problem		
									A072201	High Impedance		
							F1905	Device Revision or Replacement	A05	Mechanical Problem		
									A0722	Impedance Problem		
									A072201	High Impedance		
7536	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E1901	Bacterial Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							E1906	Unspecified Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F1903	Device Explanation	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F2303	Medication Required	A24	No Apparent Device Problem	11/06/2026	11/06/2026
					CT1150	Defibrillators	E1901	Bacterial Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							E1906	Unspecified Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F1903	Device Explanation	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F2303	Medication Required	A24	No Apparent Device Problem	11/06/2026	11/06/2026
					CT258	Implantable defibrillators	E1901	Bacterial Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							E1906	Unspecified Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F1903	Device Explanation	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F2303	Medication Required	A24	No Apparent Device Problem	11/06/2026	11/06/2026
					CT263	Cardiographs and associated devices	E1901	Bacterial Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							E1906	Unspecified Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F1903	Device Explanation	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F2303	Medication Required	A24	No Apparent Device Problem	11/06/2026	11/06/2026
					CT2866	Implantable cardiac electrical stimulators	E1901	Bacterial Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							E1906	Unspecified Infection	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F1903	Device Explanation	A24	No Apparent Device Problem	11/06/2026	11/06/2026
							F2303	Medication Required	A24	No Apparent Device Problem	11/06/2026	11/06/2026
7537	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
7538	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	Inappropriate Treatment	A060801	Signal Artifact/Noise	
										A070909	Oversensing	
										A071302	Inappropriate/Inadequate Shock/Stimulation	
										A060801	Signal Artifact/Noise	
7539	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	23/04/2026
								F09	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	23/04/2026
								F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	23/04/2026
7540	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing	23/04/2026
										A0712	Pacing Problem	
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
										A0712	Pacing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation	
7541	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
7542	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								F26	No Health Consequences or Impact	A070909	Oversensing	
						CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								F26	No Health Consequences or Impact	A070909	Oversensing	
						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								F26	No Health Consequences or Impact	A070909	Oversensing	
7543	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1905	Device Revision or Replacement	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1009	Inappropriate Treatment	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
					CT1150	Defibrillators		E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1905	Device Revision or Replacement	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1009	Inappropriate Treatment	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
					CT258	Implantable defibrillators		E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1905	Device Revision or Replacement	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1009	Inappropriate Treatment	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
					CT263	Cardiographs and associated devices		E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1905	Device Revision or Replacement	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1009	Inappropriate Treatment	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
					CT2866	Implantable cardiac electrical stimulators		E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1905	Device Revision or Replacement	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
								F1009	Inappropriate Treatment	A0709	Device Sensing Problem	07/04/2026
										A070909	Oversensing	07/04/2026
										A071302	Inappropriate/Inadequate Shock/Stimulation	07/04/2026
7544	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
								F26	No Health Consequences or Impact	A072201	High Impedance	
7545	2026		47270	Cardiac resynchronization therapy implantable defibrillator	CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0201	Product Quality Problem	
										A070504	Premature Discharge of Battery	
								F08	Hospitalization or Prolonged Hospitalization	A0201	Product Quality Problem	
										A070504	Premature Discharge of Battery	
								F1901	Additional Surgery	A0201	Product Quality Problem	

							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery		
									A0201	Product Quality Problem		
									A070504	Premature Discharge of Battery		
7546	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F08	Hospitalization or Prolonged Hospitalization	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F1009	Inappropriate Treatment	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A072201	High Impedance		
7547	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
									A150202	Malposition of Device		
							F17	Sedation	A071201	Failure to Convert Rhythm		
									A150202	Malposition of Device		
							P22	Unexpected Diagnostic Intervention	A071201	Failure to Convert Rhythm		
									A150202	Malposition of Device		
							F2203	Imaging Required	A071201	Failure to Convert Rhythm		
									A150202	Malposition of Device		
							F2306	Resuscitation	A071201	Failure to Convert Rhythm		
									A150202	Malposition of Device		
7548	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							F2307	Reprogramming of Device	A0709	Device Sensing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7549	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7550	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
							F2203	Imaging Required				
							F26	No Health Consequences or Impact				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
							F2203	Imaging Required				
							F26	No Health Consequences or Impact				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions				
							F2203	Imaging Required				
							F26	No Health Consequences or Impact				
7551	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F2203	Imaging Required	A072201	High Impedance		
							F2307	Reprogramming of Device	A072201	High Impedance		
7552	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	23/04/2026	23/04/2026
									A072201	High Impedance	23/04/2026	23/04/2026
									A072202	Low Impedance	23/04/2026	23/04/2026
							F08	Hospitalization or Prolonged Hospitalization	A0705	Battery Problem	23/04/2026	23/04/2026
									A072201	High Impedance	23/04/2026	23/04/2026
									A072202	Low Impedance	23/04/2026	23/04/2026
							F12	Serious Injury/ Illness/ Impairment	A0705	Battery Problem	23/04/2026	23/04/2026
									A072201	High Impedance	23/04/2026	23/04/2026
									A072202	Low Impedance	23/04/2026	23/04/2026
							F1905	Device Revision or Replacement	A0705	Battery Problem	23/04/2026	23/04/2026
									A072201	High Impedance	23/04/2026	23/04/2026
									A072202	Low Impedance	23/04/2026	23/04/2026
7553	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
7554	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A1206	Misconnection		
									A05	Mechanical Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1206	Misconnection		
									A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A1206	Misconnection		
									A05	Mechanical Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A1206	Misconnection		
							F26	No Health Consequences or Impact	A05	Mechanical Problem		
									A1206	Misconnection		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A05	Mechanical Problem		
							F26	No Health Consequences or Impact	A1206	Misconnection		
									A05	Mechanical Problem		

						CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A1206	Misconnection		
								F26	No Health Consequences or Impact	A05	Mechanical Problem		
										A1206	Misconnection		
										A05	Mechanical Problem		
7555	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Misconnection		
								F26	No Health Consequences or Impact	A070909	Oversensing		
7556	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070101	Failure to Capture		
										A070909	Oversensing		
								F1010	Inadequate Treatment	A070101	Failure to Capture		
										A070909	Oversensing		
7557	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7558	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
								F26	No Health Consequences or Impact	A072201	High Impedance		
7559	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
								F1009	Inappropriate Treatment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
7560	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
								F26	No Health Consequences or Impact	A070909	Oversensing		
7561	2026		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
								F0101	Therapeutic Response Decreased	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
								F0101	Therapeutic Response Decreased	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
								F0101	Therapeutic Response Decreased	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
								F0101	Therapeutic Response Decreased	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
								F0101	Therapeutic Response Decreased	A0201	Product Quality Problem		
										A070504	Premature Discharge of Battery		
										A160601	Premature Elective Replacement Indicator		
7562	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
7563	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
7564	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
								F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
								F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
								F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT263	Cardiographs and associated devices		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
								F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
					CT2866	Implantable cardiac electrical stimulators		E2403	No Clinical Signs, Symptoms or Conditions	A071201	Failure to Convert Rhythm		
								F26	No Health Consequences or Impact	A071201	Failure to Convert Rhythm		
7565	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0712	Pacing Problem		
								F1009	Inappropriate Treatment	A0712	Pacing Problem		
7566	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
								F1009	Inappropriate Treatment	A070909	Oversensing		

									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A060801	Signal Artifact/Noise		
7567	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7568	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions			27/04/2026	27/04/2026
							F08	Hospitalization or Prolonged Hospitalization			27/04/2026	27/04/2026
							F12	Serious Injury/ Illness/ Impairment			27/04/2026	27/04/2026
							F1905	Device Revision or Replacement			27/04/2026	27/04/2026
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions			27/04/2026	27/04/2026
							F08	Hospitalization or Prolonged Hospitalization			27/04/2026	27/04/2026
							F12	Serious Injury/ Illness/ Impairment			27/04/2026	27/04/2026
							F1905	Device Revision or Replacement			27/04/2026	27/04/2026
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions			27/04/2026	27/04/2026
							F08	Hospitalization or Prolonged Hospitalization			27/04/2026	27/04/2026
							F12	Serious Injury/ Illness/ Impairment			27/04/2026	27/04/2026
							F1905	Device Revision or Replacement			27/04/2026	27/04/2026
7569	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions				
							F26	No Health Consequences or Impact				
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
							F26	No Health Consequences or Impact				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
							F26	No Health Consequences or Impact				
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions				
							F26	No Health Consequences or Impact				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions				
							F26	No Health Consequences or Impact				
7570	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A1301	Failure to Read Input Signal		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A1301	Failure to Read Input Signal		
7571	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
							F12	Serious Injury/ Illness/ Impairment				
							F2307	Reprogramming of Device				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
							F12	Serious Injury/ Illness/ Impairment				
							F2307	Reprogramming of Device				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions				
							F12	Serious Injury/ Illness/ Impairment				
							F2307	Reprogramming of Device				
7572	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
							F26	No Health Consequences or Impact				
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions				
							F26	No Health Consequences or Impact				
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions				
							F26	No Health Consequences or Impact				
7573	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E0601	Arrhythmia	A070909	Oversensing		
							F23	Unexpected Medical Intervention	A070909	Oversensing		
7574	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E0601	Arrhythmia	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7575	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	05/01/2026	05/01/2026
7576	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F2203	Imaging Required	A071302	Inappropriate/Inadequate Shock/Stimulation		
7577	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
7578	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E060109	Tachycardia	A0709	Device Sensing Problem		
							F1001	Absence of Treatment	A071301	Failure to Deliver Shock/Stimulation		
									A0709	Device Sensing Problem		

								F1203	Life Threatening Illness or Injury	A071301	Failure to Deliver Shock/Stimulation		
										A0709	Device Sensing Problem		
										A071301	Failure to Deliver Shock/Stimulation		
7579	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
7580	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator		
7581	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A072001	Premature Elective Replacement Indicator		
								F12	Serious Injury/Illness/ Impairment	A072001	Electromagnetic Interference		
								F2307	Reprogramming of Device	A072001	Electromagnetic Interference		
7582	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
										A070909	Overensing		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
										A070909	Overensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7583	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0709	Device Sensing Problem		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7584	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
										A0705	Battery Problem		
7585	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A070909	Overensing		
										A070909	Overensing		
7586	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								F26	No Health Consequences or Impact	A070909	Overensing		
7587	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7588	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2123	Medical Device Site Infection	A24	No Apparent Device Problem	01/05/2026	01/05/2026
								F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	01/05/2026	01/05/2026
								F12	Serious Injury/Illness/ Impairment	A24	No Apparent Device Problem	01/05/2026	01/05/2026
								F1905	Device Revision or Replacement	A24	No Apparent Device Problem	01/05/2026	01/05/2026
7589	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT1150	Defibrillators			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT258	Implantable defibrillators			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT263	Cardiographs and associated devices			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
				CT2866	Implantable cardiac electrical stimulators			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7590	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A1107	Data Problem		
								F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
										A1107	Data Problem		
7591	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A1107	Data Problem		
								F26	No Health Consequences or Impact	A0908	Incorrect, Inadequate or Imprecise Result or Readings		
										A1107	Data Problem		
7592	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	Inappropriate Treatment	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
				CT1150	Defibrillators			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	Inappropriate Treatment	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
				CT258	Implantable defibrillators			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	Inappropriate Treatment	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
				CT263	Cardiographs and associated devices			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	Inappropriate Treatment	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
				CT2866	Implantable cardiac electrical stimulators			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	Inappropriate Treatment	A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7593	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								F26	No Health Consequences or Impact	A070909	Overensing		
				CT1150	Defibrillators			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								F26	No Health Consequences or Impact	A070909	Overensing		
				CT258	Implantable defibrillators			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Overensing		
								F26	No Health Consequences or Impact	A070909	Overensing		

					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
					CT2866	Implantable cardiac electrical stimulators	F26	No Health Consequences or Impact	A070909	Oversensing		
							E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
7594	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7595	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A070910	Undersensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7596	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1901	Additional Surgery	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7597	2026	Death	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2336	Shock				
							F02	Death				
					CT258	Implantable defibrillators	E2336	Shock				
							F02	Death				
					CT2866	Implantable cardiac electrical stimulators	E2336	Shock				
							F02	Death				
7598	2026	Death	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E0133	Stroke/CVA	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							E0306	Sepsis	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F02	Death	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F1903	Device Explanation	A24	No Apparent Device Problem	18/03/2024	18/03/2024
					CT258	Implantable defibrillators	E0133	Stroke/CVA	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							E0306	Sepsis	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F02	Death	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F1903	Device Explanation	A24	No Apparent Device Problem	18/03/2024	18/03/2024
					CT2866	Implantable cardiac electrical stimulators	E0133	Stroke/CVA	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							E0306	Sepsis	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F02	Death	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	18/03/2024	18/03/2024
							F1903	Device Explanation	A24	No Apparent Device Problem	18/03/2024	18/03/2024
7599	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A071302	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0712	Pacing Problem		
7600	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	18/05/2026	18/05/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	18/05/2026	18/05/2026
7601	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E060109	Tachycardia	A070910	Undersensing		
									A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F1908	Prolonged Surgery	A070910	Undersensing		
									A0712	Pacing Problem		
									A0713	Defibrillation/Stimulation Problem		
							F1009	Inappropriate Treatment	A070910	Undersensing		
									A0712	Pacing Problem		
7602	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A071302	Defibrillation/Stimulation Problem		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

								F26	No Health Consequences or Impact	A070909	Oversensing		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
							F26	No Health Consequences or Impact	A070909	Oversensing			
7603	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing			
								A070910	Undersensing				
								A071201	Failure to Convert Rhythm				
								A1301	Failure to Read Input Signal				
								A150202	Malposition of Device				
							F15	Recognized Device or Procedural Complication	A070909	Oversensing			
								A070910	Undersensing				
								A071201	Failure to Convert Rhythm				
								A1301	Failure to Read Input Signal				
								A150202	Malposition of Device				
							F2203	Imaging Required	A070909	Oversensing			
								A070910	Undersensing				
								A071201	Failure to Convert Rhythm				
								A1301	Failure to Read Input Signal				
								A150202	Malposition of Device				
7604	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery			
7605	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1150	Defibrillators	E020201	Anxiety	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							E2403	No Clinical Signs, Symptoms or Conditions	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F01	Change in Therapeutic Response	A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026	
								A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F08	Hospitalization or Prolonged Hospitalization	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F1901	Additional Surgery	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
					CT258	Implantable defibrillators	E020201	Anxiety	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							E2403	No Clinical Signs, Symptoms or Conditions	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F01	Change in Therapeutic Response	A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026	
								A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F08	Hospitalization or Prolonged Hospitalization	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F1901	Additional Surgery	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F1905	Device Revision or Replacement	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
					CT2866	Implantable cardiac electrical stimulators	E020201	Anxiety	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							E2403	No Clinical Signs, Symptoms or Conditions	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F01	Change in Therapeutic Response	A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026	
								A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F08	Hospitalization or Prolonged Hospitalization	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		
							F1901	Additional Surgery	A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026	
								A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026		
								A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026		
								A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026		

							F1905	Device Revision or Replacement	A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026
									A071205	Pacemaker Found in Back-Up Mode	22/05/2026	22/05/2026
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	22/05/2026	22/05/2026
									A0909	Unexpected Therapeutic Results	22/05/2026	22/05/2026
									A160503	Inappropriate or Unexpected Reset	22/05/2026	22/05/2026
7606	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E0112	Dizziness	A26	Insufficient Device Problem Information		
							E011903	Syncope/Fainting	A26	Insufficient Device Problem Information		
							E0717	Dyspnea	A26	Insufficient Device Problem Information		
7607	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			F11	Non-Serious Injury/ Illness/ Impairment	A26	Insufficient Device Problem Information		
							E060110	Ventricular Fibrillation	A070910	Undersensing		
									A0712	Pacing Problem		
							F15	Recognized Device or Procedural Complication	A070910	Undersensing		
									A0712	Pacing Problem		
7608	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7609	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F15	Recognized Device or Procedural Complication	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7610	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
7611	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7612	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
7613	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7614	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
							F26	No Health Consequences or Impact	A070909	Oversensing		
7615	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
							F08	Hospitalization or Prolonged Hospitalization	A0104	Migration or Expulsion of Device		
							F12	Serious Injury/ Illness/ Impairment	A0104	Migration or Expulsion of Device		
							F1904	Device Repositioning	A0104	Migration or Expulsion of Device		
							F2203	Imaging Required	A0104	Migration or Expulsion of Device		
7616	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7617	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing		

									A071201	Failure to Convert Rhythm		
								F08	A0713	Defibrillation/Stimulation Problem		
									A070910	Undersensing		
									A071201	Failure to Convert Rhythm		
								F12	A070910	Defibrillation/Stimulation Problem		
									A071201	Undersensing		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
								F2307	A070910	Undersensing		
									A071201	Failure to Convert Rhythm		
									A0713	Defibrillation/Stimulation Problem		
7618	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	A070504	Premature Discharge of Battery		
								F26	A070504	Premature Discharge of Battery		
7619	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	A072201	High Impedance		
								F2203	A072201	High Impedance		
								F26	A072201	High Impedance		
7620	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	A070909	Oversensing		
								F26	A070909	Oversensing		
7621	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E060110	A071201	Failure to Convert Rhythm		
									A0722	Impedance Problem		
								F15	A071201	Failure to Convert Rhythm		
									A0722	Impedance Problem		
7622	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	A071201	Failure to Convert Rhythm		
								F15	A071201	Failure to Convert Rhythm		
7623	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	A070909	Oversensing		
								F26	A070909	Oversensing		
7624	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	A090801	Signal Artifact/Noise		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
7625	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2203	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2307	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT1150	Defibrillators	E2403	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2203	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2307	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT1258	Implantable defibrillators	E2403	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2203	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2307	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT1263	Cardiographs and associated devices	E2403	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2203	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2307	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A090801	Signal Artifact/Noise		
							F2203	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F2307	A0709	Device Sensing Problem			
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
7626	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	A072201	High Impedance			
							F26	A072201	High Impedance			
7627	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E210401	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A23	Use of Device Problem		
							F08	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		
									A090801	Signal Artifact/Noise		
									A23	Use of Device Problem		
							F2203	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation		

									A090801	Signal Artifact/Noise			
						F1009	Inappropriate Treatment		A23	Use of Device Problem			
									A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
					CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F2203	Imaging Required		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F1009	Inappropriate Treatment		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F2203	Imaging Required		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F1009	Inappropriate Treatment		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
					CT263	Cardiographs and associated devices	E210401	Shock from Patient Lead(s)	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F2203	Imaging Required		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F1009	Inappropriate Treatment		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F08	Hospitalization or Prolonged Hospitalization		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F2203	Imaging Required		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
						F1009	Inappropriate Treatment		A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A23	Use of Device Problem			
7628	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery			
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery			
							F12	Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
7629	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing			
									A071302	Inappropriate/Inadequate Shock/Stimulation			
									A090801	Signal Artifact/Noise			
									A1301	Failure to Read Input Signal			
7630	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1150	Defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery			
									A27	Appropriate Device Problem Term/Code not Available			
							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery			
									A27	Appropriate Device Problem Term/Code not Available			
							F1901	Additional Surgery	A070504	Premature Discharge of Battery			
									A27	Appropriate Device Problem Term/Code not Available			
					CT258	Implantable defibrillators	E020201	Anxiety	A070504	Premature Discharge of Battery			
									A27	Appropriate Device Problem Term/Code not Available			

							F11	Non-Serious Injury/ Illness/ Impairment	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A27	Appropriate Device Problem Term/Code not Available		
									A070504	Premature Discharge of Battery		
									A27	Appropriate Device Problem Term/Code not Available		
					CT2866	implantable cardiac electrical stimulators	E020201	Anxiety	A070504	Premature Discharge of Battery		
							F11	Non-Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
									A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A27	Appropriate Device Problem Term/Code not Available		
									A070504	Premature Discharge of Battery		
7631	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7632	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
							F1010	Inadequate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
7633	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							F12	Serious Injury/ Illness/ Impairment	A0709	Device Sensing Problem		
							P2307	Reprogramming of Device	A0709	Device Sensing Problem		
7634	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2007	Fail	A070910	Undersensing		
									A0712	Pacing Problem		
									A072202	Low Impedance		
									A1301	Failure to Read Input Signal		
							F11	Non-Serious Injury/ Illness/ Impairment	A070910	Undersensing		
									A0712	Pacing Problem		
									A072202	Low Impedance		
									A1301	Failure to Read Input Signal		
7635	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem		
									A0712	Pacing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7636	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A072201	High Impedance		
							F26	No Health Consequences or Impact	A090801	Signal Artifact/Noise		
									A0709	Device Sensing Problem		
									A070910	Undersensing		
									A0712	Pacing Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
7637	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
					CT1150	Defibrillators	F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	29/05/2026	29/05/2026
7638	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2123	Medical Device Site Infection	A24	No Apparent Device Problem	12/06/2026	12/06/2026
							F08	Hospitalization or Prolonged Hospitalization	A24	No Apparent Device Problem	12/06/2026	12/06/2026
							F12	Serious Injury/ Illness/ Impairment	A24	No Apparent Device Problem	12/06/2026	12/06/2026
							F1903	Device Explanation	A24	No Apparent Device Problem	12/06/2026	12/06/2026
7639	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7640	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		
									A0711	Interrogation Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
							F26	No Health Consequences or Impact	A1301	Failure to Read Input Signal		
									A070909	Oversensing		
									A0711	Interrogation Problem		
									A072201	High Impedance		
									A090801	Signal Artifact/Noise		
									A1301	Failure to Read Input Signal		
7641	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7642	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		

							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
7643	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0709	Device Sensing Problem		
							A0712		A0712	Pacing Problem		
							F26	No Health Consequences or Impact	A0709	Device Sensing Problem		
							A0712		A0712	Pacing Problem		
7644	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0722	Impedance Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0722	Impedance Problem		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7645	2026		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
					CT1150	Defibrillators	F1901	Additional Surgery	A070504	Premature Discharge of Battery		
							E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
							F1901	Additional Surgery	A070504	Premature Discharge of Battery		
7646	2026		35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
									A0705	Battery Problem		
							F23	Unexpected Medical Intervention	A04	Material Integrity Problem		
									A0705	Battery Problem		
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
									A0705	Battery Problem		
							F23	Unexpected Medical Intervention	A04	Material Integrity Problem		
									A0705	Battery Problem		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
									A0705	Battery Problem		
							F23	Unexpected Medical Intervention	A04	Material Integrity Problem		
									A0705	Battery Problem		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
									A0705	Battery Problem		
							F23	Unexpected Medical Intervention	A04	Material Integrity Problem		
									A0705	Battery Problem		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A04	Material Integrity Problem		
									A0705	Battery Problem		
							F23	Unexpected Medical Intervention	A04	Material Integrity Problem		
									A0705	Battery Problem		
7647	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A0104	Migration or Expulsion of Device		
							F26	No Health Consequences or Impact	A0104	Migration or Expulsion of Device		
7648	2026		37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2401	Insufficient Information	A07	Electrical/Electronic Property Problem		
							F23	Unexpected Medical Intervention	A07	Electrical/Electronic Property Problem		
					CT258	Implantable defibrillators	E2401	Insufficient Information	A07	Electrical/Electronic Property Problem		
							F23	Unexpected Medical Intervention	A07	Electrical/Electronic Property Problem		
					CT2866	Implantable cardiac electrical stimulators	E2401	Insufficient Information	A07	Electrical/Electronic Property Problem		
							F23	Unexpected Medical Intervention	A07	Electrical/Electronic Property Problem		
7649	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
							F08	Hospitalization or Prolonged Hospitalization	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
							F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
7650	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A0712	Pacing Problem		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7651	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem		
									A070909	Oversensing		
							F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A0709	Device Sensing Problem		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7652	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT258	Implantable defibrillators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
									A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
					CT2866	Implantable cardiac electrical stimulators	E210401	Shock from Patient Lead(s)	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A070909	Oversensing		
									A071302	Inappropriate/Inadequate Shock/Stimulation		
7653	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A160602	Premature End-of-Life Indicator		
							F08	Hospitalization or Prolonged Hospitalization	A160602	Premature End-of-Life Indicator		
7654	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7655	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
							F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
7656	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator			E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing		

										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
										A070909	Oversensing		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
7657	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
										A070910	Undersensing		
										A072202	Low Impedance		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A070910	Undersensing		
										A072202	Low Impedance		
										A090801	Signal Artifact/Noise		
										A070909	Oversensing		
										A070910	Undersensing		
										A072202	Low Impedance		
										A090801	Signal Artifact/Noise		
7658	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
									F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7659	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E060109	Tachycardia	A0709	Device Sensing Problem	
										A071301	Failure to Deliver Shock/Stimulation		
									F1001	Absence of Treatment	A0709	Device Sensing Problem	
										A071301	Failure to Deliver Shock/Stimulation		
									F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	
										A071301	Failure to Deliver Shock/Stimulation		
7660	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E210401	Shock from Patient Lead(s)	A0709	Device Sensing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0709	Device Sensing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
									F1203	Life Threatening Illness or Injury	A0709	Device Sensing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7661	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
									F26	No Health Consequences or Impact	A072201	High Impedance	
7662	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A160503	Inappropriate or Unexpected Reset	10/06/2026
									F1001	Additional Surgery	A160503	Inappropriate or Unexpected Reset	10/06/2026
7663	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing	
										A0712	Pacing Problem		
									F1009	Inappropriate Treatment	A070910	Undersensing	
										A0712	Pacing Problem		
7664	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
										A070504	Premature Discharge of Battery		
									F26	No Health Consequences or Impact	A0705	Battery Problem	
										A070504	Premature Discharge of Battery		
7665	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
										A070504	Premature Discharge of Battery		
									F26	No Health Consequences or Impact	A0705	Battery Problem	
										A070504	Premature Discharge of Battery		
7666	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator					E210401	Shock from Patient Lead(s)	A070909	Oversensing	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
									F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
7667	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance	
									F26	No Health Consequences or Impact	A072201	High Impedance	
7668	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
										A070909	Oversensing		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
7669	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator					E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
									F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery	
										A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7670	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator					E210401	Shock from Patient Lead(s)	A0712	Pacing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
									F1009	Inappropriate Treatment	A0712	Pacing Problem	
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7671	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E210401	Shock from Patient Lead(s)	A070909	Oversensing	
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
									E2311	Discomfort	A070909	Oversensing	
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
									F1001	Absence of Treatment	A070909	Oversensing	
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
									F1009	Inappropriate Treatment	A070909	Oversensing	
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7672	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator					E060109	Tachycardia	A070910	Undersensing	
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0909	Unexpected Therapeutic Results		

								F05	Delay to Treatment/ Therapy	A070910	Undersensing		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0909	Unexpected Therapeutic Results		
								F1001	Absence of Treatment	A070910	Undersensing		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0909	Unexpected Therapeutic Results		
								F1009	Inappropriate Treatment	A070910	Undersensing		
										A0712	Pacing Problem		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A0909	Unexpected Therapeutic Results		
7673	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
								F1009	Inappropriate Treatment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
7674	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
								F26	No Health Consequences or Impact	A070504	Premature Discharge of Battery		
7675	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
								F1009	Inappropriate Treatment	A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
7676	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A070102	High Capture Threshold		
										A070909	Oversensing		
										A072202	Low Impedance		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
								F2203	Imaging Required	A070102	High Capture Threshold		
										A070909	Oversensing		
										A072202	Low Impedance		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
								F26	No Health Consequences or Impact	A070102	High Capture Threshold		
										A070909	Oversensing		
										A072202	Low Impedance		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
7677	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
								F26	No Health Consequences or Impact	A0705	Battery Problem		
										A070504	Premature Discharge of Battery		
7678	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A071302	Inappropriate/Inadequate Shock/Stimulation		
								F1009	Inappropriate Treatment	A071302	Inappropriate/Inadequate Shock/Stimulation		
7679	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator				E210401	Shock from Patient Lead(s)	A010402	Migration		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
										A1301	Failure to Read Input Signal		
								F1009	Inappropriate Treatment	A010402	Migration		
										A070909	Oversensing		
										A071302	Inappropriate/Inadequate Shock/Stimulation		
										A090801	Signal Artifact/Noise		
7680	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
								F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
								F1905	Device Revision or Replacement	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
								F2307	Reprogramming of Device	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
					CT1150	Defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
								F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
								F1905	Device Revision or Replacement	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
								F2307	Reprogramming of Device	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
					CT1258	Implantable defibrillators		E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
								F08	Hospitalization or Prolonged Hospitalization	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026
										A1301	Failure to Read Input Signal	02/07/2026	02/07/2026
								F1905	Device Revision or Replacement	A070909	Oversensing	02/07/2026	02/07/2026
										A090801	Signal Artifact/Noise	02/07/2026	02/07/2026

								F2307	Reprogramming of Device	A070909 A090801 A1301	Failure to Read Input Signal Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026 02/07/2026
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026	
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026	
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026	
							F2307	Reprogramming of Device	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026	
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026	
							F08	Hospitalization or Prolonged Hospitalization	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026	
							F1905	Device Revision or Replacement	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026	
							F2307	Reprogramming of Device	A070909 A090801 A1301	Oversensing Signal Artifact/Noise Failure to Read Input Signal	02/07/2026 02/07/2026 02/07/2026	02/07/2026 02/07/2026 02/07/2026	
7681	2026	Death	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060110	Ventricular Fibrillation	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F02	Death	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F15	Recognized Device or Procedural Complication	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F1009	Inappropriate Treatment	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
					CT258	Implantable defibrillators	E060110	Ventricular Fibrillation	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F02	Death	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F15	Recognized Device or Procedural Complication	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F1009	Inappropriate Treatment	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
					CT2866	Implantable cardiac electrical stimulators	E060110	Ventricular Fibrillation	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F02	Death	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F15	Recognized Device or Procedural Complication	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
							F1009	Inappropriate Treatment	A0712 A071201 A0713 A071302	Pacing Problem Failure to Convert Rhythm Defibrillation/Stimulation Problem Inappropriate/Inadequate Shock/Stimulation			
7682	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E060104	Bradycardia	A0705 A070504	Battery Problem Premature Discharge of Battery			
							F2307	Reprogramming of Device	A0705 A070504	Battery Problem Premature Discharge of Battery			
					CT258	Implantable defibrillators	E060104	Bradycardia	A0705 A070504	Battery Problem Premature Discharge of Battery			
							F2307	Reprogramming of Device	A0705 A070504	Battery Problem Premature Discharge of Battery			
					CT2866	Implantable cardiac electrical stimulators	E060104	Bradycardia	A0705 A070504	Battery Problem Premature Discharge of Battery			
							F2307	Reprogramming of Device	A0705 A070504	Battery Problem Premature Discharge of Battery			
7683	2026	Death	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070910	Undersensing			

										A072201	High Impedance																
										A0908	Incorrect, Inadequate or Imprecise Result or Readings																
										A0909	Unexpected Therapeutic Results																
										A070910	Undersensing																
										A072201	High Impedance																
										A0908	Incorrect, Inadequate or Imprecise Result or Readings																
										A0909	Unexpected Therapeutic Results																
										A070910	Undersensing																
										A072201	High Impedance																
										A0908	Incorrect, Inadequate or Imprecise Result or Readings																
										A0909	Unexpected Therapeutic Results																
										A070910	Undersensing																
										A072201	High Impedance																
										A0908	Incorrect, Inadequate or Imprecise Result or Readings																
										A0909	Unexpected Therapeutic Results																
										A070910	Undersensing																
										A072201	High Impedance																
										A0908	Incorrect, Inadequate or Imprecise Result or Readings																
										A0909	Unexpected Therapeutic Results																
										A070910	Undersensing																
										A072201	High Impedance																
										A0908	Incorrect, Inadequate or Imprecise Result or Readings																
										A0909	Unexpected Therapeutic Results																
										A070910	Undersensing																
										A072201	High Impedance																
										A0908	Incorrect, Inadequate or Imprecise Result or Readings																
										A0909	Unexpected Therapeutic Results																
7684	2026	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator																	
							F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator																	
							CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator															
									F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator															
									CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator													
											F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator													
											7685	2026	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator						
																		F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator						
																		CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator				
																				F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator				
																				CT1258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator		
																						F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator		
CT1263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator																						
		F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator																						
		CT12866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A160601	Premature Elective Replacement Indicator																				
				F26	No Health Consequences or Impact	A160601	Premature Elective Replacement Indicator																				
				7686	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices	E0601	Arrhythmia	A0712	Pacing Problem													
											CT1150	Defibrillators	E0601	Arrhythmia	A071202	Inaccurate Synchronization											
													CT1204	Electric Shock	A071202	Inappropriate/Inadequate Shock/Stimulation											
															A0712	Pacing Problem											
															A071202	Inaccurate Synchronization											
															A071302	Inappropriate/Inadequate Shock/Stimulation											
CT1141	Electrodes/Leads and associated devices														E0601	Arrhythmia	A0712	Pacing Problem									
															CT1204	Electric Shock	A071202	Inaccurate Synchronization									
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		A0712	Pacing Problem																								
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1210	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1211	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1212	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1213	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1214	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1215	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1216	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1217	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1218	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1219	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1220	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1221	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1222	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1223	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1224	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1225	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1226	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1227	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1228	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1229	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1230	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1231	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1232	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1233	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1234	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1235	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1236	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1237	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1238	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1239	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1240	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1241	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1242	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1243	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1244	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1245	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1246	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1247	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1248	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1249	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1250	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1251	Life Threatening illness or Injury			A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
		A071202	Inaccurate Synchronization																								
		A071302	Inappropriate/Inadequate Shock/Stimulation																								
		CT1252	Life Threatening illness or Injury	A0712	Pacing Problem																						
				A071202	Inaccurate Synchronization																						
				A071302	Inappropriate/Inadequate Shock/Stimulation																						
				A0712	Pacing Problem																						
A071202	Inaccurate Synchronization																										
A071302	Inappropriate/Inadequate Shock/Stimulation																										
CT1253	Life Threatening illness or Injury			A0712	Pacing																						

				A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT145	Cardiovascular devices	E0601	Arrhythmia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT233	Surgical	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		E2104	Electric Shock	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
CT2406	Implantable	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2407	Active implantable	E0601	Arrhythmia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT258	Implantable defibrillators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		E2104	Electric Shock	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
CT2727	Active implant devices/ancillaries	E0601	Arrhythmia	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		E2104	Electric Shock	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F1203	Life Threatening Illness or Injury	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2750	Implantable cardiac electrical stimulators and associated devices	E0601	Arrhythmia	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
		E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
		F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
				A071302	Inappropriate/Inadequate Shock/Stimulation		
		F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		
CT2866	Implantable cardiac electrical stimulators	E0601	Arrhythmia	A071302	Inappropriate/Inadequate Shock/Stimulation		
				A0712	Pacing Problem		
				A071202	Inaccurate Synchronization		

						E2104	Electric Shock	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem			
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
					F1203	Life Threatening Illness or Injury	A0712	Pacing Problem			
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
CT2985	Active					E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3001	Implantable metal					E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3002	Implantable synthetic polymer					E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3006	Implantable inorganic material					E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
CT3007	Implantable ceramic					E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
CT314	Electrically powered					E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
CT321	Long-term surgical invasive					E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		

						F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
				CT449	Generators and associated devices	E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						E2104	Electric Shock	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F1203	Life Threatening Illness or Injury	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
				CT981	Single use	E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
				CT983	Surgical invasive	E0601	Arrhythmia	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						E2104	Electric Shock	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
						F1203	Life Threatening Illness or Injury	A071302	Inappropriate/Inadequate Shock/Stimulation		
								A0712	Pacing Problem		
								A071202	Inaccurate Synchronization		
								A071302	Inappropriate/Inadequate Shock/Stimulation		
7687	2023	All other reportable incidents	37265	Dual-chamber implantable defibrillator	CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A0712	Pacing Problem		
								A090801	Signal Artifact/Noise		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A0712	Pacing Problem		
								A090801	Signal Artifact/Noise		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070909	Oversensing	
								A0712	Pacing Problem		
								A090801	Signal Artifact/Noise		
						F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	A070909	Oversensing		
								A0712	Pacing Problem		
								A090801	Signal Artifact/Noise		
			37265	Dual-chamber implantable defibrillator	CT1147	Defibrillators and associated devices					
					CT1150	Defibrillators					
					CT141	Electrodes/Leads and associated devices					
					CT145	Cardiovascular devices					
					CT233	Surgical					
					CT2406	Implantable					
					CT2407	Active implantable					
					CT258	Implantable defibrillators					
					CT2727	Active implant devices/ancillaries					
					CT2750	Implantable cardiac electrical stimulators and associated devices					
					CT2866	Implantable cardiac electrical stimulators					
					CT2965	Active					
					CT3001	Implantable metal					
					CT3002	Implantable synthetic polymer					
					CT3006	Implantable inorganic material					
					CT3007	Implantable ceramic					
					CT314	Electrically powered					
					CT321	Long-term surgical invasive					
					CT449	Generators and associated devices					
					CT981	Single use					
					CT983	Surgical invasive					
7688	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem	
								A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
						F26	No Health Consequences or Impact	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
				CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		
								A0705	Battery Problem		
								A070504	Premature Discharge of Battery		
								A0908	Incorrect, Inadequate or Imprecise Result or Readings		

							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
							F26	No Health Consequences or Impact	A0705	Battery Problem		
									A070504	Premature Discharge of Battery		
									A0908	Incorrect, Inadequate or Imprecise Result or Readings		
7689	2023	All other reportable incidents	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT1150	Defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT263	Cardiographs and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
					CT2866	Implantable cardiac electrical stimulators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
							F1903	Device Explanation	A070504	Premature Discharge of Battery	09/01/2024	09/01/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	09/01/2024	09/01/2024
7690	2023	All other reportable incidents			CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A072201	High Impedance		
							F26	No Health Consequences or Impact	A072201	High Impedance		
7691	2024	All other reportable incidents			CT1147	Defibrillators and associated devices	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2024	30/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/05/2024	30/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2024	30/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/05/2024	30/05/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2024	30/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/05/2024	30/05/2024
					CT258	Implantable defibrillators	E2403	No Clinical Signs, Symptoms or Conditions	A070504	Premature Discharge of Battery	30/05/2024	30/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/05/2024	30/05/2024
							F08	Hospitalization or Prolonged Hospitalization	A070504	Premature Discharge of Battery	30/05/2024	30/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/05/2024	30/05/2024
							F1905	Device Revision or Replacement	A070504	Premature Discharge of Battery	30/05/2024	30/05/2024
									A0908	Incorrect, Inadequate or Imprecise Result or Readings	30/05/2024	30/05/2024
7692	2024			CT258	Null		F2301	Additional Device Required	A0401	Break		
									A040101	Fracture		
									A0713	Defibrillation/Stimulation Problem		
7693	2025			CT258	Null		E2403	No Clinical Signs, Symptoms or Conditions	A090801	Signal Artifact/Noise		
							F1908	Prolonged Surgery	A090801	Signal Artifact/Noise		
7694	2026	Unanticipated serious deterioration in state of health	35852	Single-chamber implantable defibrillator	CT1010	Cardiovascular physiology analysis/mapping devices	E0133	Stroke/CVA	A27	Appropriate Device Problem Term/Code not Available		
							F08	Hospitalization or Prolonged Hospitalization	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
					CT1150	Defibrillators	E0133	Stroke/CVA	A27	Appropriate Device Problem Term/Code not Available		
							F08	Hospitalization or Prolonged Hospitalization	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
					CT258	Implantable defibrillators	E0133	Stroke/CVA	A27	Appropriate Device Problem Term/Code not Available		
							F08	Hospitalization or Prolonged Hospitalization	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
					CT263	Cardiographs and associated devices	E0133	Stroke/CVA	A27	Appropriate Device Problem Term/Code not Available		
							F08	Hospitalization or Prolonged Hospitalization	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		
					CT2866	Implantable cardiac electrical stimulators	E0133	Stroke/CVA	A27	Appropriate Device Problem Term/Code not Available		
							F08	Hospitalization or Prolonged Hospitalization	A27	Appropriate Device Problem Term/Code not Available		
							F12	Serious Injury/ Illness/ Impairment	A27	Appropriate Device Problem Term/Code not Available		

Table 2: All UK cases where the reported medical device is an implantable cardioverter defibrillators (GMDN/CT codes 35852, 37265, 47940, CT258) between 1 January 2000 up to and including 10 July 2026 broken down by patient sex

Patient sex	Number of reports
Female	174
Male	736
Unknown	6,784

Table 3 : All UK cases where the reported medical device is an implantable cardioverter defibrillators (GMDN/CT codes 35852, 37265, 47940, CT258) between 1 January 2000 up to and including 10 July 2026 broken down by patient age groups

Patient age group (yrs)	Number of reports
0 - 10	15
11 - 20	17
21 - 30	40
31 - 40	93
41 - 50	118
51 - 60	173
61 - 70	215
71 - 80	180
81 - 90	57
91 - 100	2
Unknown	6784